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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 966

[Doc. No. AMS–SC–18–0075; SC19–966–1 FR]

Tomatoes Grown in Florida; Modification of Handling Regulations

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule implements a recommendation from the Florida Tomato Committee (Committee) to change the handling regulations under the marketing order regulating the handling of tomatoes grown in Florida. This action removes the standard weight requirements for tomato containers under the handling regulations.

DATES: Effective December 4, 2019.

FOR FURTHER INFORMATION CONTACT: Steven W. Kauffman, Marketing Specialist, or Christian D. Nissen, Regional Director, Southeast Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (863) 324–3375, Fax: (863) 291–8614, or Email: *Steven.Kauffman@usda.gov* or *Christian.Nissen@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Richard.Lower@usda.gov.*

SUPPLEMENTARY INFORMATION: This final rule, pursuant to 5 U.S.C. 553, amends regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This final rule is issued under Marketing Agreement No. 125 and Marketing Order No. 966, as amended (7 CFR part 966), regulating the handling of tomatoes grown in Florida. Part 966 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Committee locally administers the marketing order and is comprised of producers operating within the production area.

The Department of Agriculture (USDA) is issuing this final rule in conformance with Executive Orders 13563 and 13175. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review. Additionally, because this final rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. See OMB's Memorandum titled ''Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled 'Reducing Regulation and Controlling Regulatory Costs' '' (February 2, 2017).

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to a marketing order may file with USDA a petition stating that the marketing order, any provision of the marketing order, or any obligation imposed in connection with the marketing order is not in accordance with law and request a modification of the marketing order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This final rule eliminates the standard weight certification requirement established under the Order. This action will relieve handlers from the time and cost associated with tomato inspection for standard weight certification at handling facilities. The Committee unanimously approved this recommendation at public meetings held on August 24, 2018, and September 6, 2018.

Section 966.52 of the Order provides authority to the Committee to establish pack and container requirements for tomatoes grown within the regulated area. This includes fixing the size, weight, capacity, dimensions, markings, or pack of the container which may be used in the packaging, transportation, sale, shipment, or other handling of tomatoes.

Section 966.323 sets forth the handling regulations for Florida tomatoes. Section 966.323(a)(3)(i) designates the container requirements for weight and establishes that § 51.1863 of the U.S. Tomato Standards (7 CFR 51.1863), which specifies the standard weight requirement, shall apply to all containers.

Section 966.60 requires Florida tomatoes to be inspected and certified by authorized representatives of the Federal or Federal-State Inspection Service (FSIS), or such other inspection service as the Secretary shall designate. The Florida Department of Agriculture and Consumer Services is an agency employing state workers who collaborate with the USDA to provide inspection services to areas not serviced by federal employees. FSIS currently certifies to standard weight as part of the inspection process.

The Committee met on August 24, 2018, and September 6, 2018, to discuss current standard weight procedures and compliance with the standard weight certification requirements. Representatives from USDA's Specialty Crop Inspection Division (SCI) and from FSIS were present to participate in the discussion. These representatives informed Committee members that some handling facilities were not maintaining compliance with the standard weight certification requirements.

The current inspection sampling rate for standard weight certification is 36 containers sampled based on a lot size of 1600 containers. FSIS currently samples eight tomato containers from each lot for grade and size inspection, and these containers are also weighed as part of the sampling for standard weight. To comply with standard weight certification procedures, an additional 28 containers should be weighed. To

lower the inspection time and cost, many tomato handlers provide an employee to sample and weigh the additional 28 containers to reach the total 36 samples required for the standard weight certification of each lot.

The containers weighed must meet the prescribed inspection requirements in 7 CFR 51.1863 for certification of the lot. Section 51.1863 specifies that when packages are marked to a net weight of 15 pounds or more, the net weight of the contents shall not be less than the designated net weight and shall not exceed the designated weight by more than 2 pounds. To allow for variations incident to proper sizing, not more than 15 percent, by count, of the packages in any lot may fail to meet the requirements for standard weight. Most of the tomatoes produced in the production area are packed in 25-pound containers.

In their discussion, Committee members stated that the current sampling rate requires costly labor and is a time-consuming process that is difficult to maintain due to the handling volume in many operations. One industry member stated that the volume of lots inspected at some handling operations can total around 50 lots in a single 24-hour period. If 50 lots were inspected in one day this would equal a total of 1800 samples selected for recording the weight. The handler's employee would be responsible for pulling and weighing 1400 of these 25-pound samples to meet the standard weight requirement. Thus, high volume handlers may have to employ multiple people to perform the weight inspections.

The labor provided by the handler expedites the certification process and is lower than the cost of having FSIS inspectors weigh the additional cartons. However, standard weight certification is still expensive to maintain. One member stated that providing the necessary employees at their handling facility to properly administer the certification program cost an extra $80,000 a year above the fees charged by FSIS inspection.

The Committee asked if it might be possible to lower the sampling rate while maintaining the certification process as the container sampling size for standard weight is several times greater than the number of containers sampled by FSIS when certifying for grade and size. SCI stated that certification at a rate lower than 36 samples would require a study that could statistically support a new sampling rate. SCI indicated a study would possibly take a year to develop, implement, and analyze the results. Committee members expressed concern over the time and cost of carrying out such a study, and that the best course of action may be to remove the requirement for standard weight inspection.

In discussing the value of the weight certification program, Committee members stated that receivers of Florida tomato shipments still perform weight inspections regardless of the required weight certification. Even with the standard weight certification, there are occasions when weight is an issue and the shipper often rectifies any discrepancies by making an adjustment to the shipment for the receiver. At both meetings, Committee members expressed that handling operations are spending thousands of dollars annually to meet the certification requirement without realizing a significant benefit from the program. Committee members stated that the expense of labor and inspection time for certification is difficult to justify since the handler already makes an adjustment for the receiver regardless of the certification.

Committee members also stated that tomato handlers outside the regulated area are not required to maintain standard weight certification. One member indicated that eliminating the standard weight requirement on Florida tomato handlers would allow the industry's inspection procedures to be more comparable to handlers outside the regulated area. Another commenter stated that most handlers are now using in-line scales to weigh each container and did not see the benefit of requiring standard weight certification.

Removing the standard weight requirement will allow handlers to avoid the time and labor costs associated with the certification process. The Committee believes there is no longer enough benefit to justify maintaining the standard weight certification, and unanimously recommended eliminating the standard weight requirements for the 2019–20 and subsequent fiscal periods.

Committee members agreed that maintaining the individual net weight requirements for containers is still a valuable component of the Order. The current net weight requirements state all tomatoes packed by a registered handler shall be packed in containers of 10, 20, and 25 pounds designated net weights. The net weight of the contents shall not be less than the designated net weight and shall not exceed the designated net weight by more than two pounds. This action will not modify that requirement.

With this action, FSIS will still sample the required containers to perform size and grade inspection along with recording the weights from each sample. FSIS shall provide a record of the weights from the eight samples inspected for size and grade upon request. The Committee noted that the eight samples weighed by FSIS will provide an independent record to reference in addition to the in-line automated weighing systems used by many handlers. The Committee believes the eight samples weighed by FSIS in conjunction with the automated weighing systems will provide ample information regarding the container weights for each lot. Further, eliminating the standard weight requirement will not preclude the handler from requesting a standard weight inspection.

Section 8e of the Act (7 U.S.C. 608e–1) provides that when certain domestically produced commodities, including tomatoes, are regulated under a Federal marketing order, imports of that commodity must meet the same or comparable grade, size, quality, and maturity requirements. No corresponding change to the import regulations is required as this action changes the container requirements.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 75 producers of Florida tomatoes in the production area and 37 handlers subject to regulation under the Order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts less than $750,000, and small agricultural service firms are defined as those whose annual receipts are less than $7,500,000 (13 CFR 121.201).

According to industry and Committee data, the average annual price for fresh Florida tomatoes during the 2017–18 season was approximately $12.56 per 25-pound container, and total fresh shipments were 25.9 million containers. Using the average price and shipment

information, the number of handlers, and assuming a normal distribution, the majority of handlers have average annual receipts of more than $7,500,000, ($12.56 times 25.9 million containers equals $325,304,000 divided by 37 handlers equals $8,792,000 per handler).

In addition, based on production data, an estimated producer price of $6.00 per 25-pound container, the number of Florida tomato producers, and assuming a normal distribution, the average annual producer revenue is above $750,000 ($6.00 times 25.9 million containers equals $155,400,000 divided by 75 producers equals $2,072,000 per producer). Thus, the majority of handlers and producers of Florida tomatoes may be classified as large entities.

This final rule eliminates the standard weight certification requirement under the Order. The Committee determined there is no longer enough benefit to justify the cost and time required for the standard weight certification. This action will enable handlers to reduce inspection time and labor costs associated with the standard weight program. This rule revises § 966.323. Authority for these changes is provided in § 966.52.

It is not anticipated that this action will impose additional costs on handlers or growers, regardless of size. This action is intended to reduce expenses incurred for labor and inspection time associated with the certification process for standard weight.

The current inspection sampling rate for standard weight certification based on a lot size of 1600 containers is 36 containers. FSIS currently samples eight tomato containers from each lot for grade and size inspection, and these containers are also weighed as part of the sampling for standard weight. To comply with standard weight certification procedures, an additional 28 containers need to be weighed. To lower the inspection time and cost, many tomato handlers provide an employee to sample and weigh the additional 28 containers to reach the total 36 samples required for the standard weight certification of each lot.

Total fresh shipments of Florida tomatoes for the 2017–18 season were 25.9 million 25-pound containers. This volume represents approximately 16,188 normal lots of tomatoes requiring inspection for standard weight. Using 2017–18 volume, this change will eliminate the requirement that inspection personnel or handler employees lift, weigh, and record approximately 453,265 25-pound containers during a similar season. This analysis illustrates the laborious nature involved in the standard weight inspection and certification process.

Avoiding the time and labor costs associated with standard weight certification will reduce expenses for the Florida tomato industry. This action will reduce the labor required for the inspection process by thousands of hours every year, reducing the cost for handlers. The expense of labor for inspection can vary widely between handler employees and the FSIS. However, one Committee member stated that this action will save his handling operation $80,000 every year. This action is expected to lower handler cost associated with the inspection process. The benefits of this rule are expected to be equally available to all Florida fresh tomato handlers, regardless of size.

The Committee considered an alternative to this action. Prior to this recommendation, the Committee discussed lowering the sampling size for the standard weight certification program with the SCI. However, after further discussion on the inspection process and the time it could possibly take to review, the Committee determined the standard weight program no longer provided enough benefit to justify the cost and time required for certification. Therefore, the alternative was rejected.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0178 Vegetable and Specialty Crops. No changes in those requirements are necessary as a result of this action. Should any changes become necessary, they would be submitted to OMB for approval.

This final rule will not impose any additional reporting or recordkeeping requirements on either small or large Florida tomato handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. As noted in the initial regulatory flexibility analysis, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule. No public comments were received regarding the initial regulatory flexibility analysis.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

The Committee's meetings were widely publicized throughout the Florida tomato industry, and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the August 24 and September 6, 2018, meetings were public meetings, and all entities, both large and small, were able to express their views on this issue.

A proposed rule concerning this action was published in the **Federal Register** on April 16, 2019 (84 FR 15528). Copies of the proposed rule were sent via email to Committee members and Florida tomato handlers. Additionally, the rule was made available through the internet by USDA and the Office of the Federal Register. A 30-day comment period ending May 16, 2019, was provided to allow interested persons to respond to the proposal.

During the comment period, five comments were received in response to the proposal. Four of the comments favored the proposed change, but expressed some concerns over the potential impact of the change. Three of these comments supported the action from a financial and economic standpoint. Two commenters stated the net weight requirements were enough to ensure quality.

The concerns raised included the impact on quality and labor. Two commenters were concerned about consumers receiving a quality product. One commenter supported lifting the regulation for small entities, but that inspection and certification be maintained for large entities. This action only removes the standard weight requirement. All lots of tomatoes will still be inspected for quality and net weight, helping to ensure consumers receive a consistent product meeting the established quality standards. In its discussions, the Committee indicated without a standard weight certification, the net weights will still be checked by the receiver and adjustments can be make accordingly. Further, eliminating the standard weight requirement will not preclude the handler from requesting a standard weight inspection if that is preferred by the customer.

Two comments questioned the impact of this change on the labor force. During the Committee's deliberations, handlers described assigning some employees to assist in the process as a cost-saving measure compared to having FSIS provide additional staff to do the sampling. Committee members stated the current sampling rate is a costly, time-consuming process that is difficult

to maintain due to the handling volume in many operations. The Committee anticipates improved efficiency in inspection time and labor costs.

One individual also recommended developing an alternative process for certification that could allow handlers to continue receiving certification. As previously stated, the Committee discussed alternative means for certification and determined the standard weight program no longer provided enough benefit to justify the cost and time required to develop that alternative.

The remaining comment pertained to issues not applicable to the proposed rule. Accordingly, based on the comments received, no changes will be made to the rule as proposed.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant matter presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 966

Marketing agreements, Reporting and recordkeeping requirements, Tomatoes.

For the reasons set forth in the preamble, 7 CFR part 966 is amended as follows:

PART 966—TOMATOES GROWN IN FLORIDA

■ 1. The authority citation for 7 CFR part 966 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Revise § 966.110 to read as follows:

§ 966.110 Order.

Order means Order No. 966 (§§ 966.1 through 966.92) regulating the handling of tomatoes grown in Florida, also referenced in this part as *marketing order and agreement.*

■ 3. Revise § 966.111 to read as follows:

§ 966.111 Marketing Agreement.

The Marketing Agreement associated with Order No. 966 is Marketing Agreement No. 125.

■ 4. Amend § 966.323 by revising paragraphs (a)(3)(i) and the last two sentences of paragraph (g) to read as follows:

§ 966.323 Handling regulation.

* * * * *

(a) * * *

(3) * * *

(i) All tomatoes packed by a registered handler shall be packed in containers of 10, 20, and 25 pounds designated net weights. The net weight of the contents shall not be less than the designated net weight and shall not exceed the designated net weight by more than two pounds.

* * * * *

(g) * * * *U.S. tomato standards* means the revised United States Standards for Fresh Tomatoes (7 CFR 51.1855 through 51.1877) effective October 1, 1991, as amended, or variations thereof specified in this section, provided that § 51.1863 shall not apply to tomatoes covered by this part. Other terms in this section shall have the same meaning as when used in this part and the U.S. tomato standards.

Dated: September 23, 2019.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2019–21015 Filed 11–1–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0747; Product Identifier 2019–NE–26–AD; Amendment 39–19778; AD 2019–21–12]

RIN 2120–AA64

Airworthiness Directives; BRP-Rotax GmbH & Co KG Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain BRP-Rotax GmbH & Co KG (Rotax) 914 F2, 914 F3, and 914 F4 model engines. This AD requires removal of a certain exhaust valve and its replacement with a part eligible for installation. This AD was prompted by a report of a broken exhaust valve installed on a Rotax 914 model engine. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 19, 2019.

The FAA must receive comments on this AD by December 19, 2019.

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

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

For service information identified in this final rule, contact BRP-Rotax GmbH & Co KG, Rotaxstrasse 1, A–4623 Gunskirchen, Austria; phone: +43 7246 601 0; fax: +43 7246 601 9130; email: *airworthiness@brp.com;* internet: *www.flyrotax.com.* You may view this service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7759. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0747.

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–2019–0747; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), the regulatory 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 FURTHER INFORMATION CONTACT: Wego Wang, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7134; fax: 781–238–7199; email: *wego.wang@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

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

AD No. 2018–0265R1, dated January 9, 2019 (and corrected January 10, 2019) (referred to after this as ''the MCAI''), to address an unsafe condition for the specified products. The MCAI states:

A broken exhaust valve has been reported on a non-certified Rotax 914 UL2–01 engine. Subsequent investigation identified deviation in the manufacturing process of the affected exhaust valve.

This condition, if not corrected, could lead to in-flight shut down, possibly resulting in a forced landing with consequent damage to the aeroplane and injury to occupants.

Due to similarity of design, this condition may affect also Rotax 915 iSc3 A, 915 iSc3 B engines and Rotax 914 F2, 914 F3 and 914 F4 engines.

To address this potential unsafe condition, BRP-Rotax issued the ASB, later revised, providing applicable instructions, and EASA issued AD 2018–0265–E requiring replacement of affected exhaust valves, and prohibiting installation thereof on an engine.

Since that [EASA] AD was issued, it has been determined that only exhaust valve P/N 854113 of certain lot numbers are affected, and BRP-Rotax revised the ASB accordingly (now at revision 2).

You may obtain further information by examining the MCAI in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0747.

Related Service Information

The FAA reviewed BRP-Rotax Alert Service Bulletin (ASB) ASB–915 i A–003R2/ASB–915 i B–003R2/ASB–914–054R2 (single document), dated December 21, 2018. The ASB describes procedures for replacing the exhaust valve.

FAA's Determination

This product has been approved by EASA, and is 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 the MCAI and service information referenced above. The FAA is issuing this AD because it evaluated all the relevant information provided by EASA and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

AD Requirements

This AD requires, within 10 flight hours or 3 months after the effective date of this AD, whichever occurs first, removal from service of certain exhaust valves and replacement with a part eligible for installation.

FAA's Justification and Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because no domestic operators use this product. It is unlikely that the FAA will receive any adverse comments or useful information about this AD from U.S. operators. Therefore, the FAA finds good cause that notice and opportunity for prior public comment are unnecessary. In addition, for this same reason, the FAA finds that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment. However, the FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under the **ADDRESSES** section. Include the docket number FAA–2019–0747 and Product Identifier 2019–NE–26–AD at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this final rule. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

The FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact received about this final rule.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 0 engines installed on airplanes of U.S. registry.

In the event an affected engine becomes installed on a U.S.-registered product, the FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replace exhaust valve	6 work-hours × $85 per hour = $510	$1,500	$2,010	$0

Authority for This Rulemaking

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

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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to engines, propellers, and associated appliances to the Manager, Engine and Propeller Standards Branch, Policy and Innovation Division.

Regulatory Findings

This AD will not have federalism implications under Executive Order

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

For the reasons discussed above, I certify this AD:

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 December 1, 2019 [Amended]

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

2019–21–12 BRP-Rotax GmbH & Co KG (Type Certificate previously held by BRP-Powertrain GmbH & Co KG; Bombardier-Rotax GmbH): Amendment 39–19778; Docket No. FAA–2019–0747; Product Identifier 2019–NE–26–AD.

(a) Effective Date

This AD is effective November 19, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to BRP-Rotax GmbH & Co KG (Type certificate previously held by BRP-Powertrain GmbH & Co KG, Bombardier-Rotax GmbH) (Rotax) Model 914 F2, 914 F3, and 914 F4 engines, with an exhaust valve part number (P/N) 854113 that has a production lot number 0317 or 0517.

(d) Subject

Joint Aircraft System Component (JASC) Code 8530, Reciprocating Engine Cylinder Section.

(e) Unsafe Condition

This AD was prompted by a report of a broken exhaust valve installed on a Rotax 914 model engine. The FAA is issuing this AD to prevent failure of the exhaust valve. The unsafe condition, if not addressed, could result in loss of engine thrust control and reduced control of the airplane.

(f) Compliance

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

(g) Required Actions

Within 10 flight hours or 3 months after the effective date of this AD, whichever occurs first, remove from service each exhaust valve P/N 854113 that has a production lot number 0317 or 0517, and replace with a part eligible for installation.

Note 1 to paragraph (g): For guidance on replacing the exhaust valve, refer to the Accomplishment Instructions, paragraphs 3.1 through 3.6, of Rotax Alert Service Bulletin ASB–915 i A–003R2/ASB–915 i B–003R2/ASB–914–054R2 (single document), dated December 21, 2018.

(h) Installation Prohibition

After the effective date of this AD, do not install an exhaust valve P/N 854113 that has a production lot number 0317 or 0517 on any engine.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD. You may email your request to: *ANE-AD-AMOC@faa.gov.*

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

(j) Related Information

(1) For more information about this AD, contact Wego Wang, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7134; fax: 781–238–7199; email: *wego.wang@faa.gov.*

(2) Refer to European Union Aviation Safety Agency (EASA) AD No. 2018–0265R1, dated January 9, 2019 (and corrected January 10, 2019), for more information. You may examine the EASA AD in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating it in Docket No. FAA–2019–0747.

(k) Material Incorporated by Reference

None.

Issued in Burlington, Massachusetts, on October 29, 2019.

Robert J. Ganley,

Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2019–24029 Filed 11–1–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31279; Amdt. No. 3876]

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 November 4, 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 November 4, 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 October 18, 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 number	FDC date	Subject
5-Dec-19 ..	IA	Algona	Algona Muni	9/0173	9/26/19	VOR/DME–A, Amdt 7B.
5-Dec-19 ..	NE	Ogallala	Searle Field	9/0265	9/26/19	RNAV (GPS) RWY 8, Amdt 2B.
5-Dec-19 ..	NE	Ogallala	Searle Field	9/0266	9/26/19	RNAV (GPS) RWY 13, Orig-C.
5-Dec-19 ..	NE	Ogallala	Searle Field	9/0267	9/26/19	RNAV (GPS) RWY 26, Amdt 2B.
5-Dec-19 ..	NE	Ogallala	Searle Field	9/0268	9/26/19	RNAV (GPS) RWY 31, Orig-B.
5-Dec-19 ..	GA	Gainesville	Lee Gilmer Memorial	9/0558	10/9/19	RNAV (GPS) RWY 5, Amdt 1.
5-Dec-19 ..	TX	Plainview	Hale County	9/0736	9/26/19	RNAV (GPS) RWY 4, Orig-A.
5-Dec-19 ..	AK	Unalakleet	Unalakleet	9/1227	9/26/19	LOC RWY 15, Amdt 5.
5-Dec-19 ..	ND	Valley City	Barnes County Muni	9/1262	9/26/19	RNAV (GPS) RWY 13, Orig.

AIRAC date	State	City	Airport	FDC number	FDC date	Subject
5-Dec-19 ..	ND	Valley City	Barnes County Muni	9/1264	9/26/19	RNAV (GPS) RWY 31, Orig.
5-Dec-19 ..	ND	Tioga	Tioga Muni	9/1284	9/26/19	RNAV (GPS) RWY 30, Amdt 1B.
5-Dec-19 ..	HI	Kailua/Kona ...	Ellison Onizuka Kona Intl At Keahole ...	9/2576	9/25/19	VOR OR TACAN RWY 17, Orig-B.
5-Dec-19 ..	HI	Kailua/Kona ...	Ellison Onizuka Kona Intl At Keahole ...	9/2581	9/25/19	VOR OR TACAN RWY 35, Orig-B.
5-Dec-19 ..	IL	Centralia	Centralia Muni	9/2647	9/26/19	RNAV (GPS) RWY 18, Amdt 1B.
5-Dec-19 ..	IN	Jeffersonville ..	Clark Rgnl	9/2701	9/26/19	NDB RWY 18, Amdt 3.
5-Dec-19 ..	IA	Waterloo	Waterloo Rgnl	9/2779	9/26/19	VOR RWY 12, Amdt 10B.
5-Dec-19 ..	IA	Waterloo	Waterloo Rgnl	9/2782	9/26/19	VOR RWY 24, Amdt 16C.
5-Dec-19 ..	IA	Waterloo	Waterloo Rgnl	9/2783	9/26/19	ILS OR LOC RWY 12, Amdt 10A.
5-Dec-19 ..	IA	Waterloo	Waterloo Rgnl	9/2785	9/26/19	LOC BC RWY 30, Amdt 12.
5-Dec-19 ..	MI	Detroit	Detroit Metropolitan Wayne County	9/3713	10/11/19	RNAV (RNP) X RWY 21L, Amdt 1.
5-Dec-19 ..	OH	Dayton	Dayton-Wright Brothers	9/3755	10/11/19	RNAV (GPS) RWY 20, Orig.
5-Dec-19 ..	CA	Los Angeles ...	Whiteman	9/4031	9/25/19	VOR–A, Amdt 2A.
5-Dec-19 ..	AK	Ambler	Ambler	9/4436	9/26/19	RNAV (GPS) RWY 1, Amdt 1A.
5-Dec-19 ..	CA	Stockton	Stockton Metropolitan	9/4956	9/25/19	ILS OR LOC RWY 29R, Amdt 22.
5-Dec-19 ..	OK	Pauls Valley ...	Pauls Valley Muni	9/5287	9/26/19	RNAV (GPS) RWY 35, Amdt 1.
5-Dec-19 ..	GA	Gainesville	Lee Gilmer Memorial	9/5865	9/26/19	NDB RWY 5, Amdt 5B.
5-Dec-19 ..	GA	Gainesville	Lee Gilmer Memorial	9/5873	9/26/19	RNAV (GPS) RWY 23, Amdt 1.
5-Dec-19 ..	ND	Tioga	Tioga Muni	9/7699	9/26/19	RNAV (GPS) RWY 12, Orig.
5-Dec-19 ..	GA	Atlanta	Hartsfield—Jackson Atlanta Intl	9/8725	9/26/19	RNAV (GPS) PRM RWY 9L (SIMULTANEOUS CLOSE PARALLEL), Orig-C.

[FR Doc. 2019–23950 Filed 11–1–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31278; Amdt. No. 3875]

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 November 4, 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 November 4, 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 October 18, 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 5 December 2019*

Adak Island, AK, Adak, ILS Y OR LOC Y RWY 23, Orig
Adak Island, AK, Adak, ILS Z OR LOC Z RWY 23, Orig
Anchorage, AK, Merrill Field, Takeoff Minimums and Obstacle DP, Amdt 2
Mena, AR, Mena Intermountain Muni, RNAV (GPS) RWY 17, Amdt 1
Phoenix, AZ, Phoenix-Mesa Gateway, RNAV (GPS) RWY 30R, Orig
Fernandina Beach, FL, Fernandina Beach Muni, RNAV (GPS) RWY 4, Orig
Fernandina Beach, FL, Fernandina Beach Muni, RNAV (GPS) RWY 13, Amdt 2C
Fernandina Beach, FL, Fernandina Beach Muni, RNAV (GPS) RWY 22, Amdt 1D
Chicago/Rockford, IL, Chicago/Rockford Intl, ILS OR LOC RWY 1, Amdt 29
Chicago/Rockford, IL, Chicago/Rockford Intl, LOC BC RWY 19, Amdt 16
Chicago/Rockford, IL, Chicago/Rockford Intl, NDB RWY 1, Amdt 25D, CANCELLED
Coffeyville, KS, Coffeyville Muni, NDB RWY 35, Amdt 1A, CANCELLED
Coffeyville, KS, Coffeyville Muni, RNAV (GPS) RWY 35, Orig-B
Mora, MN, Mora Muni, RNAV (GPS) RWY 35, Orig-C
Tower, MN, Tower Muni, RNAV (GPS) RWY 8, Amdt 1
Tower, MN, Tower Muni, RNAV (GPS) RWY 26, Orig-C
Elkin, NC, Elkin Muni, RNAV (GPS) RWY 7, Orig-A
Sylva, NC, Jackson County, RNAV (GPS) RWY 33, Amdt 1
Broken Bow, NE, Broken Bow Muni/Keith Glaze Fld, Takeoff Minimums and Obstacle DP, Amdt 4
Zanesville, OH, Zanesville Muni, ILS OR LOC RWY 22, Amdt 2
Zanesville, OH, Zanesville Muni, RNAV (GPS) RWY 22, Orig-A
Poteau, OK, Robert S Kerr, RNAV (GPS) RWY 18, Amdt 1
Poteau, OK, Robert S Kerr, RNAV (GPS) RWY 36, Amdt 1
Poteau, OK, Robert S Kerr, VOR/DME–A, Orig-A, CANCELLED
Greer, SC, Greenville Spartanburg Intl, ILS OR LOC RWY 4, ILS RWY 4 (SA CAT I), ILS RWY 4 (CAT II), ILS RWY 4 (CAT III), Amdt 25
Greer, SC, Greenville Spartanburg Intl, ILS OR LOC RWY 22, Amdt 6
Greer, SC, Greenville Spartanburg Intl, RNAV (GPS) RWY 4, Amdt 3
Greer, SC, Greenville Spartanburg Intl, RNAV (GPS) RWY 22, Amdt 2
Rapid City, SD, Rapid City Rgnl, RNAV (GPS) RWY 14, Amdt 2C
Cisco, TX, Gregory M Simmons Memorial, RNAV (GPS) Y RWY 18, Orig-A
Cisco, TX, Gregory M Simmons Memorial, RNAV (RNP) Z RWY 18, Amdt 1A
Eagle Lake, TX, Eagle Lake, RNAV (GPS) RWY 35, Amdt 2
Eagle Lake, TX, Eagle Lake, Takeoff Minimums and Obstacle DP, Amdt 2
Fort Worth, TX, Fort Worth Spinks, ILS OR LOC RWY 35L, Amdt 2B
Renton, WA, Renton Muni, RNAV (GPS) RWY 34, Orig
Middleton, WI, Middleton Muni—Morey Field, RNAV (GPS) RWY 10, Amdt 2

[FR Doc. 2019–23951 Filed 11–1–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9880]

RIN 1545–BO02

Removal of Section 385 Documentation Regulations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document removes final regulations setting forth minimum documentation requirements that ordinarily must be satisfied in order for certain related-party interests in a corporation to be treated as indebtedness for Federal tax purposes. This document also adopts conforming amendments to other final regulations to reflect the removal of the documentation regulations. The final regulations removed or amended by this

document generally affect corporations that issue purported indebtedness to related corporations or partnerships.

DATES: These regulations are effective November 4, 2019.

FOR FURTHER INFORMATION CONTACT: Austin Diamond-Jones, (202) 317–5363 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act (44 U.S.C. 3501–3521), approval for the information collection included in these regulations had been requested under control number 1545–2267. Because of the removal of the final documentation regulations, the information burden has been removed and control number 1545–2267 is no longer needed.

Background

I. Overview

Section 385(a) of the Internal Revenue Code (Code) authorizes the Secretary to ''prescribe such regulations as may be necessary or appropriate to determine whether an interest in a corporation is to be treated for purposes of [the Code] as stock or indebtedness (or as in part stock and in part indebtedness).'' Section 385(b) requires such regulations to ''set forth factors which are to be taken into account in determining with respect to a particular factual situation whether a debtor-creditor relationship exists or a corporation-shareholder relationship exists.'' Section 385(b) also enumerates a nonexclusive list of factors potentially to be included in those regulations.

On October 21, 2016, the Department of the Treasury (Treasury Department) and the IRS published final and temporary regulations (T.D. 9790) under section 385 in the **Federal Register** (81 FR 72858). The final and temporary regulations under section 385 (Section 385 Regulations) include rules set forth in § 1.385–2, which establish minimum documentation requirements that ordinarily must be satisfied in order for purported debt obligations among related parties to be treated as debt for Federal tax purposes (Documentation Regulations). The Section 385 Regulations also include §§ 1.385–3, 1.385–3T, and 1.385–4T, which treat as stock certain debt that is issued by a corporation to a controlling shareholder in a distribution or in another related-party transaction that achieves an economically similar result (Distribution Regulations).

The Documentation Regulations, as proposed, would have been applicable with respect to interests issued or deemed issued on or after the date of finalization. However, commenters expressed concern that, if the Documentation Regulations were to be applicable as of that date, taxpayers would lack adequate time to prepare for compliance with the requirements set forth in those regulations. To assist taxpayers in their preparation for the Documentation Regulations, the Treasury Department and the IRS made the regulations applicable with respect to interests issued or deemed issued after January 1, 2018. See §§ 1.385–1(f), 1.385–2(d)(2)(iii), and 1.385–2(i).

II. Executive Order 13789

Executive Order 13789 (E.O. 13789), issued on April 21, 2017, instructed the Secretary to review all significant tax regulations issued on or after January 1, 2016, and to take concrete action to alleviate the burdens of regulations that (i) impose an undue financial burden on U.S. taxpayers; (ii) add undue complexity to the Federal tax laws; or (iii) exceed the statutory authority of the IRS. E.O. 13789 further instructed the Secretary to submit to the President within 60 days a report (First Report) that identifies regulations that meet these criteria. Notice 2017–38 (2017–30 I.R.B. 147 (July 24, 2017)) included the Section 385 Regulations in a list of eight regulations identified by the Secretary in the First Report as meeting at least one of the first two criteria specified in E.O. 13789. In addition, E.O. 13789 instructed the Secretary to submit to the President a second report (Second Report) that recommended specific actions to mitigate the burden imposed by regulations identified in the First Report.

III. Additional Delay in Application of Documentation Regulations

As noted in Part I of this Background section, the Treasury Department and the IRS had originally delayed the applicability date of the Documentation Regulations to help taxpayers prepare for compliance with those rules. Taxpayers, however, continued to express concern regarding the timing and potential application of the Documentation Regulations. Based on those continued concerns, and in light of the contemplated additional action regarding the Section 385 Regulations that resulted from E.O. 13789 review, the Treasury Department and the IRS determined that a further delay in the application of the Documentation Regulations would be appropriate. Accordingly, in Notice 2017–36 (2017–33 I.R.B. 208 (August 14, 2017)), the Treasury Department and the IRS announced their intent to amend the Documentation Regulations to delay the applicability of the regulations for 12 months, making the regulations applicable only to interests issued or deemed issued on or after January 1, 2019.

IV. Proposed Removal of Documentation Regulations

The Second Report announced that the Treasury Department and the IRS were considering a proposal to revoke the finalized Documentation Regulations. See Executive Order 13789—Second Report to the President on Identifying and Reducing Tax Regulatory Burdens, 82 FR 48013, 48016 (October 16, 2017). On September 24, 2018, the Treasury Department and the IRS published a notice of proposed rulemaking (REG–130244–17) in the **Federal Register** (83 FR 48265) that proposed removing the Documentation Regulations and adopting conforming amendments to other final regulations to reflect the removal of the Documentation Regulations (Proposed Regulations). The preamble to the Proposed Regulations provided that ''taxpayers may rely on these proposed regulations, in their entirety, until the date a Treasury decision adopting these regulations as final regulations is published in the **Federal Register**'' (Reliance Provision). Proposed Regulations, 83 FR at 48267.

Summary of Comments

The Treasury Department and the IRS received three written comments regarding the Proposed Regulations. Two of the comments supported removal of the Documentation Regulations, while one comment opposed removal. In connection with the Proposed Regulations, the Treasury Department and the IRS also received a written comment addressing solely the Distribution Regulations.

The single commenter that opposed removal of the Documentation Regulations argued that the Proposed Regulations would hamper the ability of the IRS to counter earnings stripping, and result in significant decreases in Federal revenue. In addition, the commenter asserted that the removal likely would reduce the overall perceived legitimacy of the U.S. tax system, and consequently reduce voluntary compliance. The commenter further argued that removal of the Documentation Regulations would prove unnecessary because of (i) the delayed applicability date provided by Notice 2017–36 and (ii) substantial, taxpayer-favorable modifications included in the finalized Documentation Regulations.

The two commenters that supported removal of the Documentation Regulations contended that the regulations fail to balance appropriately (i) the burdens imposed on taxpayers with (ii) the expected benefits to the Federal government described in the preceding paragraph. Both commenters expressed their appreciation for the Reliance Provision, and emphasized that application of the Documentation Regulations would have imposed onerous compliance burdens and costs on taxpayers. One commenter also asserted that the Reliance Provision appropriately reduced administrative burdens on the IRS.

The Treasury Department and the IRS have considered each of the competing arguments and concerns set forth by the commenters and have determined that the burdens imposed on taxpayers by the Documentation Regulations outweigh the regulations' intended benefits. As a result, this document adopts the Proposed Regulations with no change as final regulations. The Treasury Department and the IRS, however, continue to consider the issues addressed by the Documentation Regulations.

After this further review, the Treasury Department and the IRS may propose a modified version of the Documentation Regulations. In any modified version, the Treasury Department and the IRS would substantially simplify and streamline the proposal to minimize taxpayer burdens, while ensuring the collection of sufficient documentation and other information necessary for tax administration purposes. The Treasury Department and the IRS welcome comments regarding approaches that would most effectively achieve that balance. Any modified version of the Documentation Regulations would be proposed with a prospective effective date to allow sufficient lead-time for taxpayers to design and implement systems to comply with those regulations.

Effective Date

The removal of § 1.385–2 and the conforming modifications are effective as of November 4, 2019.

Statement of Availability of IRS Documents

IRS Notices cited in this document are published in the Internal Revenue Bulletin and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *http://www.irs.gov.*

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

Executive Order 13777 directs agencies to alleviate unnecessary regulatory burdens placed on the American people by managing the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations. Executive Orders 13771, 13563, and 12866 direct agencies to prudently manage the cost of planned regulations by assessing 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.

The final regulations have been designated as subject to review under Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Treasury Department and the Office of Management and Budget (OMB) regarding review of tax regulations. OMB has determined that the final regulations are not a significant regulatory action. This final rule is an Executive Order 13771 deregulatory action.

A. Background

On October 21, 2016, the Treasury Department and the IRS published final and temporary regulations (T.D. 9790) under section 385 in the **Federal Register** (81 FR 72858). The final and temporary regulations under section 385 include rules set forth in § 1.385–2, which establish minimum documentation requirements that ordinarily must be satisfied in order for purported debt obligations among related parties to be treated as debt for Federal tax purposes (that is, the Documentation Regulations).

These final regulations withdraw the Documentation Regulations, and thereby remove the requirements set forth in those regulations on taxpayers with respect to certain transactions related to debt issuance. If applicable, the Documentation Regulations would have prescribed the nature of the documentation necessary to substantiate the Federal income tax treatment of related-party interests as indebtedness, including documentation of factors analogous to those found in third-party loan agreements. In general, to comply with the Documentation Regulations, taxpayers would have needed to provide or otherwise establish the following: (*1*) Evidence of an unconditional and binding obligation to make interest and principal payments on certain fixed dates; (*2*) that the holder of the loan had the rights of a creditor, including rights superior to shareholders in the case of dissolution; (*3*) a reasonable expectation of the borrower's ability to repay the loan; and (*4*) evidence of conduct consistent with a debtor-creditor relationship. The Documentation Regulations would have applied to relevant intercompany debt issued by U.S. borrowers beginning in 2019, and would have required that the taxpayer's documentation for a given tax year be prepared by the time the borrower's Federal income tax return is filed.

Since the issuance of the Documentation Regulations, Congress enacted the Tax Cuts and Jobs Act, Public Law 115–97, 131 Stat. 2054 (2017) (TCJA). While the final regulations do not implement any provisions of the TCJA, the final regulations would interact with the TCJA. There are several provisions of the TCJA that reduced the tax advantages of conducting activity as part of a foreign controlled domestic corporation (FCDC) rather than in a domestically controlled company (DCC), and thus may affect the economic efficiency of the Documentation Regulations and, analogously, the removal of those regulations. First, for taxable years beginning after December 31, 2017, the TCJA reduced the statutory corporate tax rate from 35 percent to 21 percent, which lowers the effective tax rate for DCCs more than for FCDCs. Second, the ability of FCDCs to strip earnings out of the United States through the use of deductions for interest expense was significantly reduced by the TCJA through amendments to section 163(j) of the Internal Revenue Code. See section 13301(a) of the TCJA, 131 Stat. 2054, 2117–21. Specifically, the TCJA amendments to section 163(j) (*1*) eliminated the debt-equity ratio safe harbor, (*2*) reduced the maximum net interest deductions' share of adjusted taxable income from 50 percent to 30 percent, (*3*) limited all, rather than just related-party, interest deductions, and (*4*) eliminated the carryforward of excess limitation under pre-TCJA section 163(j). The TCJA's Base Erosion Anti-abuse Tax (BEAT) further reduces the tax advantage to deducting interest expense. See section 14401(a) of the TCJA, 131 Stat. 2054, 2226–32. Thus, the benefits of the Documentation

Regulations in reducing foreign acquisitions of U.S. assets and interest stripping were reduced by the TCJA.

B. Need for the Final Regulations

These final regulations implement the fifth deregulatory action identified for further consideration in the Second Report issued pursuant to E.O. 13789. Accordingly, the final regulations are needed to remove the Documentation Regulations.

C. Overview of the Final Regulations

These final regulations remove the Documentation Regulations, which set forth minimum documentation requirements that ordinarily must be satisfied in order for certain related-party interests in a corporation to be treated as indebtedness for Federal tax purposes. In addition, the final regulations adopt conforming amendments to other final regulations to reflect the removal of the Documentation Regulations.

D. Economic Analysis

1. Baseline

The Treasury Department and the IRS have assessed the benefits and costs of these final regulations compared to a no-action baseline that reflects anticipated Federal income tax-related behavior in the absence of these final regulations.

2. Summary of Economic Effects

These final regulations provide compliance cost savings for some taxpayers by eliminating the need to document relevant transactions in a prescribed manner. The behavior of taxpayers that nevertheless continue to document such transactions would not be changed to any measurable degree. While the removal of the Documentation Regulations may lead to an increase in investment in the United States, this effect is likely to be small given that a body of other regulations continue to cover the terms of that investment. The final regulations may increase costs of the IRS in administering the Distribution Regulations and potentially lead to more noncompliance by some taxpayers.

An analysis discussing the anticipated economic effects of these regulations was included in the preamble to the Proposed Regulations. See Proposed Regulations, 83 FR at 48267–69. The Treasury Department and the IRS received no substantive comments regarding that analysis in response to the Proposed Regulations. The analysis included herein presents the analysis set forth in those Proposed Regulations.

3. Number of Affected Taxpayers

The Treasury Department and the IRS project that approximately 6,300 large C corporations are likely to be affected by these regulations. This estimate is based on the number of corporations that have sufficient assets ($100 million) or revenue ($50 million) or are publicly traded such that they would have been required to document the relevant transactions.

4. Monetized Estimates of Compliance Burden Effects From Documentation Regulations

The Treasury Department and the IRS estimate that removal of the Documentation Regulations will reduce taxpayer compliance costs by $924 million over the period 2019–2028 (undiscounted nominal total). The net present value of the compliance cost savings is $773 million and $685 million ($2018) using real discount rates of 3 percent and 7 percent, respectively. These amounts are $90.6 million and $97.5 million on an annualized basis, again based on 3 percent and 7 percent real rates, respectively. See below the ''Change in Annual Compliance Costs'' table.

These estimates include an ongoing reduction in compliance costs and a reduction in the start-up cost equal to four times the annual ongoing compliance cost savings. In addition, the analysis includes a sensitivity analysis in which the compliance costs are estimated for a 90-percent interval around our best estimate. First, the distributional characteristics of critical parameters used to produce the estimate are evaluated. Then, Monte Carlo simulations are used to vary the parameter values. Finally, alternative high and low estimates are computed based on parameter values at either end of the 90-percent range.

TABLE—CHANGE IN ANNUAL COMPLIANCE COSTS

Estimated change in annual compliance costs (annualized value, $2018 million)	Fiscal years 2019 to 2028 (3% real discount rate)	Fiscal years 2019 to 2028 (7% real discount rate)
Central estimate	−$90.6	−$97.5
High estimate	−113.3	−121.9
Low estimate	−68.0	−73.1

Technical note: In this rulemaking, the Treasury Department made technical adjustments relative to the Documentation Regulations in calculating the annualized compliance cost estimates. The cost stream in this rulemaking is in 2018 dollars, reflects a two-year delay in effective date (relative to the previous estimates), and applies real discount rates of 3 percent and 7 percent. Technical adjustments account for part of the difference in the estimates between the rulemakings.

5. Higher Tax Administrative Costs for the IRS

The reduced loan documentation required of large corporations as a result of the removal of the Documentation Regulations will reduce the ability of the IRS to more effectively administer the tax laws by making it more difficult for the IRS to evaluate whether purported loans are properly treated as debt for Federal tax purposes. This will raise the cost of auditing and evaluating the tax returns of companies engaged in these transactions.

6. Other Economic Effects

a. Reduced Tax Compliance

As a result of the final regulations, taxpayers will not be required to comply with the Documentation Regulations. Therefore, such taxpayers will not need to satisfy the documentation requirements with respect to relevant transactions formerly addressed by the Documentation Regulations. That lack of documentation likely will slightly reduce voluntary compliance by taxpayers to report accurately the Federal income tax consequences of such transactions. The resulting expected revenue reduction is $407 million over the period 2019 to 2028 (undiscounted nominal total). The annualized value of the revenue reduction is $35.4 million and $34.5 million ($2018) using real discount rates of 3 percent and 7 percent, respectively. The revenue effects were estimated

using the methodology described in the preamble to the Section 385 Regulations, although the estimate presented herein covers 2019 to 2028 and reflects factors that changed as a result of the TCJA as well as other technical adjustments.

b. Efficiency and Growth Effects

The removal of the Documentation Regulations will increase, to some extent, the tax advantage some foreign owners have over some domestic owners of U.S. assets, and consequently may increase the propensity for foreign acquisitions and ownership of U.S. assets that are motivated by tax considerations rather than economics. By increasing the ability to undertake tax-motivated acquisitions or ownership structures, removal of the Documentation Regulations may slightly reduce the incentive for assets to be owned or managed by those most capable of putting the assets to their highest-valued use. Moreover, removal of the Documentation Regulations may put purely domestic U.S. firms on less even tax footing than their foreign-owned competitors operating in the United States.

On the other hand, removal of the Documentation Regulations may slightly reduce the effective tax rate and compliance costs on investment in the United States. While the magnitude of this reduction is small, to the extent that the reduction increases new capital investment in the United States its effects would be efficiency enhancing.

II. Regulatory Flexibility Act

As described in more detail in this section, pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), the Treasury Department and the IRS hereby certify that these final regulations will not have a significant economic impact on a substantial number of small entities.

The Documentation Regulations, as finalized, were made applicable with respect to interests issued or deemed issued on or after January 1, 2018. See Background section, part I. In Notice 2017–36, the Treasury Department and the IRS further delayed the applicability of the Documentation Regulations by making the regulations applicable only to interests issued or deemed issued on or after January 1, 2019. See Background section, part III. Because of the Reliance Provision, the Documentation Regulations are not applicable to any interests issued by any taxpayer, unless such taxpayer chooses to apply the regulations despite the Reliance Provision. See Background section, part IV.

The Documentation Regulations apply to large corporate groups (specifically, those that are publicly traded, or have assets exceeding $100 million or annual total revenue exceeding $50 million in its expanded group), thus limiting the scope of small entities affected. The Documentation Regulations apply to financial institutions, which are considered small entities under the Regulatory Flexibility Act if they have less than $550 million in assets. See 13 CFR 121.201. The Treasury Department and the IRS believe that the Documentation Regulations do not affect a substantial number of small entities other than small financial institutions. Even if the Documentation Regulations affected a substantial number of small entities in that sector, the economic impact of this rule would be minimal because the final regulations adopt the Proposed Regulations, which remove the Documentation Regulations and permit taxpayers not to apply such regulations until adoption of these final regulations. Accordingly, this final rule will not have a significant economic impact on a substantial number of small entities.

Pursuant to section 7805(f), the proposed regulations preceding these final regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business and no comments were received.

III. Unfunded Mandates Reform Act

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 2019, that threshold is approximately $164 million. This final rule does not include any mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

IV. Executive Order 13132: Federalism

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 final 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.

Drafting Information

The principal author of the final regulations is Austin Diamond-Jones, Office of the Associate Chief Counsel (Corporate). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by removing the sectional authority for § 1.385–2 to read, in part, as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.385–1 is amended by:

■ 1. Revising paragraph (a), the last sentence of paragraph (c), the last sentence of paragraph (c)(4)(iv), paragraph (d)(1)(i), the first sentence of paragraph (d)(1)(ii), and paragraphs (d)(1)(iii) and (d)(1)(iv)(A); and

■ 2. Removing and reserving paragraph (d)(2)(i).

The revisions read as follows:

§ 1.385–1 General provisions.

(a) *Overview of section 385 regulations.* This section and §§ 1.385–3 through 1.385–4T (collectively, the section 385 regulations) provide rules under section 385 to determine the treatment of an interest in a corporation as stock or indebtedness (or as in part stock and in part indebtedness) in particular factual situations. Paragraph (b) of this section provides the general rule for determining the treatment of an interest based on provisions of the Internal Revenue Code and on common law, including the factors prescribed under common law. Paragraphs (c), (d), and (e) of this section provide definitions and rules of general application for purposes of the section 385 regulations. Section 1.385–3 sets forth additional factors that, when present, control the determination of whether an interest in a corporation that is held by a member of the corporation's expanded group is treated (in whole or in part) as stock or indebtedness.

* * * * *

(c) * * * For additional definitions that apply for purposes of their respective sections, see §§ 1.385–3(g) and 1.385–4T(e).

* * * * *

(4) * * *

(iv) * * * For purposes of the section 385 regulations, a corporation is a member of an expanded group if it is described in this paragraph (c)(4)(iv) immediately before the relevant time for determining membership (for example, immediately before the issuance of a debt instrument (as defined in § 1.385–3(g)(4)) or immediately before a distribution or acquisition that may be subject to § 1.385–3(b)(2) or (3)).

* * * * *

(d) * * *

(1) * * *

(i) *In general.* If a debt instrument (as defined in § 1.385–3(g)(4)) is deemed to be exchanged under the section 385 regulations, in whole or in part, for stock, the holder is treated for all Federal tax purposes as having realized an amount equal to the holder's adjusted basis in that portion of the debt instrument as of the date of the deemed exchange (and as having basis in the stock deemed to be received equal to that amount), and, except as provided in paragraph (d)(1)(iv)(B) of this section, the issuer is treated for all Federal tax purposes as having retired that portion of the debt instrument for an amount equal to its adjusted issue price as of the date of the deemed exchange. In addition, neither party accounts for any accrued but unpaid qualified stated interest on the debt instrument or any foreign exchange gain or loss with respect to that accrued but unpaid qualified stated interest (if any) as of the deemed exchange. This paragraph (d)(1)(i) does not affect any rules in Title 26 of the United States Code that otherwise apply to the debt instrument prior to the date of the deemed exchange (for example, this paragraph (d)(1)(i) does not affect the issuer's deduction of accrued but unpaid qualified stated interest otherwise deductible prior to the date of the deemed exchange). Moreover, the stock issued in the deemed exchange is not treated as a payment of accrued but unpaid original issue discount or qualified stated interest on the debt instrument for Federal tax purposes.

(ii) * * * Notwithstanding the first sentence of paragraph (d)(1)(i) of this section, the rules of § 1.988–2(b)(13) apply to require the holder and the issuer of a debt instrument that is deemed to be exchanged under the section 385 regulations, in whole or in part, for stock to recognize any exchange gain or loss, other than any exchange gain or loss with respect to accrued but unpaid qualified stated interest that is not taken into account under paragraph (d)(1)(i) of this section at the time of the deemed exchange. * * *

(iii) *Section 108(e)(8).* For purposes of section 108(e)(8), if the issuer of a debt instrument is treated as having retired all or a portion of the debt instrument in exchange for stock under paragraph (d)(1)(i) of this section, the stock is treated as having a fair market value equal to the adjusted issue price of that portion of the debt instrument as of the date of the deemed exchange.

(iv) * * *

(A) A debt instrument that is issued by a disregarded entity is deemed to be exchanged for stock of the regarded owner under § 1.385–3T(d)(4);

* * * * *

§ 1.385–2 [Removed]

■ **Par. 3.** Section 1.385–2 is removed.

■ **Par. 4.** Section 1.385–3 is amended by revising paragraph (g)(4) to read as follows:

§ 1.385–3 Transactions in which debt proceeds are distributed or that have a similar effect.

* * * * *

(g) * * *

(4) *Debt instrument.* The term debt instrument means an interest that would, but for the application of this section, be treated as a debt instrument as defined in section 1275(a) and § 1.1275–1(d).

* * * * *

■ **Par. 5.** Section 1.1275–1 is amended by revising the last sentence of paragraph (d) to read as follows:

§ 1.1275–1 Definitions.

* * * * *

(d) * * * See § 1.385–3 for rules that treat certain instruments that otherwise would be treated as indebtedness as stock for Federal tax purposes.

* * * * *

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

Approved: September 30, 2019.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2019–23817 Filed 10–31–19; 4:15 pm]

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DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

31 CFR Part 1010

RIN 1506–AB42

Imposition of Fifth Special Measure Against the Islamic Republic of Iran as a Jurisdiction of Primary Money Laundering Concern

AGENCY: Financial Crimes Enforcement Network, (''FinCEN''), Treasury.

ACTION: Final rule.

SUMMARY: FinCEN is issuing this final rule, pursuant to Section 311 of the USA PATRIOT Act, to prohibit the opening or maintaining of correspondent accounts in the United States for, or on behalf of, Iranian financial institutions, and the use of foreign financial institutions' correspondent accounts at covered U.S. financial institutions to process transactions involving Iranian financial institutions.

DATES: This final rule is effective November 14, 2019.

FOR FURTHER INFORMATION CONTACT: The FinCEN Resource Center, (800) 949–2732, refer to FDMS Docket No. FinCEN–2019–0002.

SUPPLEMENTARY INFORMATION:

I. Statutory Provisions

On October 26, 2001, the President signed into law the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, Public Law 107–56 (USA PATRIOT Act). Title III of the USA PATRIOT Act amended the anti-money laundering (AML) provisions of the Bank Secrecy Act (BSA), codified at 12 U.S.C. 1829b, 12 U.S.C. 1951–1959, and 31 U.S.C. 5311–5314, 5316–5332, to promote the prevention, detection, and prosecution of international money laundering and the financing of terrorism. Regulations implementing the BSA appear at 31 CFR chapter X. The authority of the Secretary of the Treasury (Secretary) to administer the BSA and its implementing regulations has been delegated to FinCEN.

Section 311 of the USA PATRIOT Act (Section 311), codified at 31 U.S.C. 5318A, grants FinCEN the authority, upon finding that reasonable grounds exist for concluding that a jurisdiction outside of the United States, one or more financial institutions operating outside of the United States, one or more classes of transactions within or involving a jurisdiction outside of the United States, or one or more types of

accounts is of primary money laundering concern, to require domestic financial institutions and domestic financial agencies to take certain ''special measures.'' The five special measures enumerated in Section 311 are preventative safeguards that defend the U.S. financial system from money laundering and terrorist financing. FinCEN may impose one or more of these special measures in order to protect the U.S. financial system from these threats. Special measures one through four, codified at 31 U.S.C. 5318A(b)(1)–(b)(4), impose additional recordkeeping, information collection, and reporting requirements on covered U.S. financial institutions. The fifth special measure, codified at 31 U.S.C. 5318A(b)(5), allows FinCEN to prohibit, or impose conditions on, the opening or maintaining in the U.S. of correspondent or payable-through accounts for, or on behalf of, a foreign bank, if such correspondent account or payable-through account involves the foreign jurisdiction, financial institution, class of transaction, or type of account found to be of primary money laundering concern.

Before making a finding that reasonable grounds exist for concluding that a jurisdiction is of primary money laundering concern, the Secretary is required to consult with both the Secretary of State and the Attorney General.[1] The Secretary must also consider such information as the Secretary determines to be relevant, including the following potentially relevant factors:

- Evidence that organized criminal groups, international terrorists, or entities involved in the proliferation of weapons of mass destruction (''WMD'') or missiles have transacted business in that jurisdiction;
- the extent to which that jurisdiction or financial institutions operating in that jurisdiction offer bank secrecy or special regulatory advantages to nonresidents or nondomiciliaries of that jurisdiction;
- the substance and quality of administration of the bank supervisory and counter-money laundering laws of that jurisdiction;
- the relationship between the volume of financial transactions occurring in that jurisdiction and the size of the economy of the jurisdiction;
- the extent to which that jurisdiction is characterized as an offshore banking or secrecy haven by credible international organizations or multilateral expert groups;
- whether the United States has a mutual legal assistance treaty with that jurisdiction, and the experience of U.S. law enforcement officials and regulatory officials in obtaining information about transactions originating in or routed through or to such jurisdiction; and
- the extent to which that jurisdiction is characterized by high levels of official or institutional corruption.

Upon finding that a jurisdiction is of primary money laundering concern, the Secretary may require covered financial institutions to take one or more special measures. In selecting which special measure(s) to take, the Secretary ''shall consult with the Chairman of the Board of Governors of the Federal Reserve System, any other appropriate federal banking agency (as defined in Section 3 of the Federal Deposit Insurance Act), the Secretary of State, the Securities and Exchange Commission, the Commodity Futures Trading Commission, the National Credit Union Administration Board, and at the sole discretion of the Secretary, such other agencies and interested parties as the Secretary may find appropriate.'' [2] In imposing the fifth special measure, the Secretary must do so ''in consultation with the Secretary of State, the Attorney General, and the Chairman of the Board of Governors of the Federal Reserve System.'' [3]

In addition, in selecting which special measure(s) to take, the Secretary shall consider the following factors:

- Whether similar action has been or is being taken by other nations or multilateral groups;
- whether the imposition of any particular special measure would create a significant competitive disadvantage, including any undue cost or burden associated with compliance, for financial institutions organized or licensed in the United States;
- the extent to which the action or the timing of the action would have a significant adverse systemic impact on the international payment, clearance, and settlement system, or on legitimate business activities involving the particular jurisdiction, institution, class of transactions, or type of account; and
- the effect of the action on U.S. national security and foreign policy.[4]

II. Public Participation

FinCEN's decision to take this action as a final rule is consistent with the Administrative Procedure Act (APA) and in the interest of U.S. foreign policy. Section 311's fifth special measure ''may be imposed only by regulation.'' [5] The APA exempts regulations involving ''a military or foreign affairs function of the United States'' from its requirements for notice of proposed rulemaking, the opportunity for public participation, and a 30 day delay in effective date.[6] As set forth in more detail below, this rule imposes a special measure with regard to the jurisdiction of the Islamic Republic of Iran (Iran). Iran is the subject of a national emergency declaration identifying it as an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States and is the subject of multiple Executive Orders identifying it as a supporter of terrorism as well as other malign activities.[7] The special measure described herein relates to important foreign policy goals of the U.S. Government, namely to deny the Iranian regime resources to support terrorism, develop nuclear weapons and/or the proliferation of weapons of mass destruction, advance its ballistic missile program, oppress the Iranian people, and fuel conflicts in Syria, Afghanistan, Yemen and elsewhere. Rapid imposition of the fifth special measure pursuant to Section 311, without any procedural delays caused by soliciting public comments concerning U.S. foreign policy, will further protect the U.S. financial system from Iran by ensuring that U.S. financial institutions are not exposed to Iran's ongoing illicit finance activities, including its support for international terrorism. Because this rule involves a foreign affairs function, it is exempt from the provisions of the APA requiring notice of proposed rulemaking, the opportunity for public participation, and a 30 day delay in effective date. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) does not apply. To ensure orderly implementation, FinCEN will delay its effective date until November 14, 2019.

III. Summary of the Final Rule

This final rule sets forth (i) FinCEN's finding that Iran is a jurisdiction of primary money laundering concern pursuant to Section 311, and (ii) FinCEN's imposition of a prohibition under the fifth special measure on the opening or maintaining of

[1] 31 U.S.C. 5318A(c)(1).

[2] 31 U.S.C. 5318A(a)(4)(A).

[3] 31 U.S.C. 5318A(b)(5).

[4] 31 U.S.C. 5318A(a)(4)(B).

[5] 31 U.S.C. 5318A(a)(2)(C).

[6] 5 U.S.C. 553(a)(1).

[7] *See, e.g.,* E.O. 12957, ''Prohibiting Certain Transactions With Respect to the Development of Iranian Petroleum Resources'' (1995); E.O. 13848, ''Reimposing Certain Sanctions With Respect to Iran'' (2018); E.O. 13876, ''Imposing Sanctions With Respect to Iran'' (2019).

correspondent accounts in the United States for, or on behalf of, Iranian financial institutions, and the use of foreign financial institutions' correspondent accounts at covered U.S. financial institutions to process transactions involving Iranian financial institutions.

IV. Treasury Actions Involving Iran

The U.S. Department of the Treasury (Treasury) has taken numerous actions to publicly highlight and counter Iran's malign activities, including implementation of a multitude of sanctions programs and issuance of several advisories. On November 5, 2018, the United States fully re-imposed the sanctions on Iran that had been lifted or waived under the Joint Comprehensive Plan of Action (JCPOA).[8] However, Iran has continued to evade these sanctions, fund terror and destabilizing activities, and advance its ballistic missile development. As a result, Treasury and the U.S. Department of State (State Department) have continued imposing sanctions on Iranian persons, as well as persons in third countries who have continued to transact with Iran, or who have acted for or on behalf of designated Iranian persons.

On November 28, 2011, FinCEN issued an NPRM proposing the implementation of the fifth special measure against Iran as a jurisdiction of primary money laundering concern pursuant to Section 311.[9] [10]

V. Finding Iran To Be a Jurisdiction of Primary Money Laundering Concern

Based on information available to FinCEN, including both public and non-public reporting,[11] and after considering the factors listed in the 311 statute and performing the requisite interagency consultations with the Secretary of State and Attorney General as required by 31 U.S.C. 5318A(c)(1), FinCEN finds that reasonable grounds exist for concluding that Iran is a jurisdiction of primary money laundering concern. While FinCEN has considered all factors set forth in Section 5318A(c)(2)(A), a discussion of those factors most relevant to this finding follows.

Iran's Abuse of the International Financial System

Iran has developed covert methods for accessing the international financial system and pursuing its malign activities, including misusing banks and exchange houses, operating procurement networks that utilize front or shell companies, exploiting commercial shipping, and masking illicit transactions using senior officials, including those at the Central Bank of Iran (CBI). Iran has also used precious metals to evade sanctions and gain access to the financial system, and may in the future seek to exploit virtual currencies. These efforts often serve to fund the Islamic Revolutionary Guard Corps (IRGC), its Islamic Revolutionary Guard Corps Qods Force (IRGC–QF), Lebanese Hizballah (Hizballah), Hamas, the Taliban and other terrorist groups.[12]

Factor 1: Evidence That Organized Criminal Groups, International Terrorists, or Entities Involved in the Proliferation of Weapons of Mass Destruction or Missiles Have Transacted Business in That Jurisdiction [13]

a. Role of CBI Officials in Facilitating Terrorist Financing

Senior CBI officials have played a critical role in enabling illicit networks, using their official capacity to procure hard currency and conduct transactions for the benefit of the IRGC–QF and its terrorist proxy groups. The CBI has been complicit in these activities, including providing billions of U.S. dollars (USD) and euros to the IRGC–QF, Hizballah and other terrorist organizations. Since at least 2016, the CBI has provided the IRGC–QF with the vast majority of its foreign currency. During 2018 and early 2019, the CBI transferred several billion USD and euros from the Iranian National Development Fund (NDF) to the IRGC–QF.

In September 2019, Treasury designated the CBI and NDF under its counterterrorism authority, Executive Order (E.O.) 13224, as amended by E.O. 13886. The Iranian government established the NDF to serve the welfare of the Iranian people by allocating revenues from oil and gas sales to economic investments, but has instead used the NDF as a slush fund for the IRGC–QF, for years disbursing hundreds of millions of USD in cash to the IRGC–QF. In coordination with the CBI, the NDF provided the IRGC–QF with half a billion USD in 2017 and hundreds of millions of USD in 2018.

In November 2018, Treasury designated nine persons—including two CBI officials—involved in an international network through which Iran provided millions of barrels of oil to Syria via Russian companies, in exchange for Syria's facilitation of the movement of hundreds of millions of USD to the IRGC–QF, for onward transfer to Hizballah and Hamas.[14] The designations highlighted, as the Secretary stated, that ''[CBI] officials continue to exploit the international financial system, and in this case even used a company whose name suggests a trade in humanitarian goods as a tool to facilitate financial transfers supporting this oil scheme.'' [15]

The scheme was centered on Syrian national Mohammad Amer Alchwiki and his Russia-based company, Global Vision Group. Global Vision worked with Russian state-owned company Promsyrioimport to facilitate shipments of Iranian oil to Syria. To assist the Bashar Al-Assad regime in paying Russia for this service, Iran sent funds to Russia through Alchwiki and Global Vision. To conceal its involvement, the CBI made payments to Mir Business Bank [16] using Iran-based Tadbir Kish Medical and Pharmaceutical Company. Following the CBI's transfer of funds from Tadbir Kish to Global Vision, Global Vision transferred payments to Promsyrioimport.

CBI senior officials were crucial to the scheme's success. CBI International Department Director Rasul Sajjad and CBI Vice Governor for International Affairs Hossein Yaghoobi both assisted in facilitating Alchwiki's transfers. First Deputy Director of Promsyrioimport Andrey Dogaev worked closely to

[8] The JCPOA was finalized on July 14, 2015, between the U.S., China, France, Germany, Russia, the United Kingdom, the European Union, and Iran to ensure that Iran's nuclear program would be exclusively peaceful. The U.S. announced it would cease its participation in the JCPOA on May 8, 2018.

[9] *See* 76 FR 72878 (November 28, 2011), Imposition of Special Measure Against the Islamic Republic of Iran as a Jurisdiction of Primary Money Laundering Concern.

[10] FinCEN intends to issue a separate document withdrawing the 2011 NPRM.

[11] FinCEN may submit classified information used in support of a Section 311 finding and special measure(s) determination to a reviewing court *ex parte* and *in camera*. *See* Section 376 of the Intelligence Authorization Act for fiscal year 2004, Public Law 108–177 (amending U.S.C. 5318A by adding new paragraph (f)).

[12] *Advisory on the Iranian Regime's Illicit and Malign Activities and Attempts to Exploit the Financial System,* FinCEN, October 11, 2018.

[13] 31 U.S.C. 5318A(c)(2) states that in making a finding that a jurisdiction is of primary money laundering concern, the Secretary shall consider in addition to such information as the Secretary determines to be relevant, the potentially relevant factors enumerated in section 5318A(c)(2)(A). Due to Iran's role as a state sponsor of terrorism and the extraterritorial nature of its malign conduct, FinCEN determined it was relevant to consider terrorism and weapons proliferation transactions with the government of Iran in addition to such transactions in the jurisdiction of Iran, as discussed in this section.

[14] *Treasury Designates Illicit Russia-Iran Oil Network Supporting the Assad Regime, Hizballah, and Hamas,* November 20, 2018, *https://home.treasury.gov/news/press-release/sm553.*

[15] *Id.*

[16] Treasury designated Mir Business Bank on November 5, 2018. It is a wholly-owned subsidiary of Iran's Bank Melli, which was designated for acting as a conduit for payments to the IRGC–QF.

coordinate the sale of Iranian crude oil to Syria with Yaghoobi, who has a history of working with Hizballah in Lebanon and has coordinated financial transfers to Hizballah with IRGC–QF and Hizballah personnel. Using this scheme, the network exported millions of barrels of Iranian oil into Syria, and funneled millions of USD between the CBI and Alchwiki's Mir Bank account in Russia.[17]

Separately, in May 2018, in connection with a scheme to move millions of USD for the IRGC–QF, Treasury designated the then-governor of the CBI, Valiollah Seif, the assistant director of CBI's international department, Ali Tarzali, Iraq-based al-Bilad Islamic Bank, Aras Habib, Al-Bilad's Chairman and Chief Executive, and Muhammad Qasir, a Hizballah official. Treasury designated them as Specially Designated Global Terrorists (SDGTs) pursuant to E.O. 13224. Treasury stated that Seif had covertly funneled millions of USD on behalf of the IRGC–QF through al-Bilad Bank to support Hizballah's radical agenda, an action that undermined the credibility of his commitment to protecting CBI's integrity.[18]

Also in May 2018, Treasury, in a joint action with the United Arab Emirates (UAE), designated nine Iranian individuals and entities involved in an extensive currency exchange network that was procuring and transferring millions in USD-denominated bulk cash to the IRGC–QF to fund its malign activities and regional proxy groups. The CBI was complicit in the IRGC–QF's scheme, actively supported the network's currency conversion, and enabled it to access funds that it held in its foreign bank accounts.[19]

The CBI and senior CBI officials have a history of using exchange houses to conceal the origin of funds and procure foreign currency for the IRGC–QF. During periods of heightened sanctions pressures, Iran has relied heavily on third-country exchange houses and trading companies to move funds to evade sanctions. Iran uses them to act as money transmitters in processing funds transfers through the United States to third-country beneficiaries, in support of business with Iran that is in violation of U.S. sanctions targeting Iran. These third-country exchange houses or trading companies frequently lack their own U.S. Dollar accounts and instead rely on the correspondent accounts of their regional banks to access the U.S. financial system.[20]

Additionally, according to information provided to FinCEN, in 2017, the CBI coordinated with Hizballah to arrange a single EUR funds transfer to a Turkish bank worth over $50 million USD.

b. IRGC's Abuse of the International Financial System

Iran is the world's leading state sponsor of terrorism, providing material support to numerous Treasury-designated terrorist groups, including Hizballah, Hamas, and the Taliban, often via its IRGC–QF. The IRGC–QF is an elite unit within the IRGC, the military and internal security force created after the Islamic Revolution. IRGC–QF personnel advise and support pro-Iranian regime factions worldwide, including several which, like Hizballah, Hamas, and the Taliban, the United States has similarly designated as terrorists.

Treasury has designated the IRGC pursuant to several E.O.s: E.O. 13382 in connection with its support to Iran's ballistic missile and nuclear programs; E.O. 13553 for serious human rights abuses by the Iranian government; E.O. 13606 in connection with grave human rights abuses; E.O. 13224 for global terrorism, and consistent with the Countering America's Adversaries Through Sanctions Act, for its support of the IRGC–QF. Treasury has designated the IRGC–QF pursuant to E.O. 13224 for providing material support to terrorist groups, including the Taliban, E.O. 13572 for support to the Syrian General Intelligence Directorate, the Assad regime's civilian intelligence service, and E.O. 13553 for serious human rights abuses by the Iranian government.

In April 2019, the State Department designated the IRGC, including the IRGC–QF, as a Foreign Terrorist Organization (FTO).[21] It was the first time that the United States designated a part of another government as an FTO—an action that highlighted Iran's use of terrorism as a central tool of its statecraft and an essential element of its foreign policy. The IRGC is integrally woven into the Iranian economy, operating institutions and front companies worldwide, so that the profits from seemingly legitimate business deals may actually fund Iranian terrorism.[22]

The IRGC–QF's misuse of the international financial system to enable its nefarious activities include numerous examples that have occurred in the United States. In May 2018, the United States and the UAE took joint action to disrupt an extensive currency exchange network that was procuring and transferring millions in USD-denominated bulk cash to the IRGC–QF to fund its malign activities and regional proxy groups. Treasury designated nine Iranian individuals and entities, and noted that key CBI officials supported the transfer of funds.[23]

On November 5, 2018, in connection with the re-imposition of U.S. nuclear-related sanctions that had been lifted or waived under the JCPOA, Treasury sanctioned over 700 individuals, entities, aircraft, and vessels in its largest ever single-day action targeting Iran. The action included the designations of more than 70 Iran-linked financial institutions and their foreign and domestic subsidiaries. Bank Melli was among those banks designated pursuant to E.O. 13224 for assisting in, sponsoring, or providing financial, material, or technological support for, or other services to or in support of, the IRGC–QF. As of 2018, the equivalent of billions of USD in funds had transited IRGC–QF controlled accounts at Bank Melli. Moreover, Bank Melli had enabled the IRGC and its affiliates to move funds into and out of Iran, while the IRGC–QF, using Bank Melli's presence in Iraq, had used Bank Melli to pay Iraqi Shia militant groups.[24]

On November 20, 2018, Treasury designated nine individuals and entities in an international network through which the Iranian regime worked with Russian companies to provide millions of barrels of oil to the Assad regime in Syria. The Assad regime, in turn, facilitated the movement of hundreds of

[17] *Treasury Designates Illicit Russia-Iran Oil Network Supporting the Assad Regime, Hizballah, and Hamas,* November 20, 2018, *https://home.treasury.gov/news/press-release/sm553.*

[18] *Treasury Targets Iran's Central Bank Governor and an Iraqi Bank Moving Millions of Dollars for IRGC-Qods Force,* May 15, 2018, *https://home.treasury.gov/news/press-release/sm0385.*

[19] *United States and United Arab Emirates Disrupt Large Scale Currency Exchange Network Transferring Millions of Dollars to the IRGC–QF,* May 10, 2018, *https://home.treasury.gov/news/press-releases/sm0383.*

[20] *Advisory on the Iranian Regime's Illicit and Malign Activities and Attempts to Exploit the Financial System,* FinCEN, October 11, 2018.

[21] *Designation of the Islamic Republic Revolutionary Guard Corps,* April 8, 2019, *https://www.state.gov/designation-of-the-islamic-revolutionary-guard-corp/.*

[22] *Intent to Designate the Islamic Revolutionary Guard Corps as a Foreign Terrorist Organization,* April 8, 2019, *https://www.state.gov/intent-to-designate-the-islamic-revolutionary-guard-corps-as-a-foreign-terrorist-organization/.*

[23] *United States and United Arab Emirates Disrupt Large Scale Currency Exchange Network Transferring Millions of Dollars to the IRGC–QF,* May 10, 2018, *https://home.treasury.gov/news/press-releases/sm0383.*

[24] *U.S. Government Fully Re-Imposes Sanctions on the Iranian Regime As Part of Unprecedented U.S. Economic Pressure Campaign,* November 5, 2018, *https://home.treasury.gov/news/press-releases/sm541.*

millions of USD to the IRGC–QF for onward transfer to Hamas and Hizballah.[25]

In March 2019, Treasury took action against 25 individuals and entities, including a network of Iran, UAE, and Turkey-based front companies that transferred over a billion USD and euros to the IRGC, IRGC–QF and Iran's Ministry of Defense and Armed Forces Logistics (MODAFL). The action included a designation of Ansar Bank, an Iranian bank controlled by the IRGC, and its currency exchange arm, Ansar Exchange, for providing banking services to the IRGC–QF.[26]

In June 2019, Treasury designated an Iraq-based IRGC–QF financial conduit, South Wealth Resources Company (SWRC), which trafficked hundreds of millions of U.S. dollars' worth of weapons to IRGC–QF-backed militias. SWRC and its two Iraqi associates covertly facilitated the IRGC–QF's access to the Iraqi financial system to evade sanctions, while also generating profits in the form of commission payments for a Treasury-designated advisor to the IRGC–QF's commander, Qasem Soleimani. Soleimani has run weapons smuggling networks, participated in bombings of Western embassies, and attempted assassinations in the region.[27]

Iran's activities include acts of attempted violence in the United States. In October 2011, pursuant to E.O. 13224, Treasury designated four senior IRGC–QF officers and Mansoor Arbabsiar, a naturalized U.S. citizen, for plotting to assassinate the Saudi Arabian Ambassador to the United States. In an example that laid bare the risks financial institutions take when transacting with Iran, payment for the assassination reached Arbabsiar from Tehran via two wire transfers totaling approximately $100,000 USD, sent from a non-Iranian foreign bank to a U.S. bank.[28]

c. Iranian Support to Terrorists

Hizballah

Despite its attempts to portray itself as a legitimate political entity, Hizballah is first and foremost a terrorist organization, responsible for the most American deaths by terrorism prior to the September 11, 2001 terrorist attacks. A Lebanon-based Shia militant group formed in Lebanon in 1982, Hizballah was responsible for the suicide truck bombings of the U.S. Embassy in Beirut, Lebanon in April 1983, the U.S. Marine barracks in Beirut in October 1983, the U.S. Embassy annex in Beirut in 1984, the hijacking of TWA 847 in 1985, and the Khobar Towers attack in Saudi Arabia in 1996.[29] Iran provides upwards of $700 million USD annually toward Hizballah's estimated $1 billion USD budget.

Hizballah is listed in the annex to E.O. 12947 from January 1995, ''Prohibiting Transactions With Terrorists Who Threaten to Disrupt The Middle East Peace Process.'' The State Department designated Hizballah in October 1997 as an FTO and in October 2001 as an SDGT pursuant to E.O. 13224. Treasury issued additional sanctions against Hizballah in August 2012 pursuant to E.O. 13582 (which targets the government of Syria and its supporters) specifically in connection with Hizballah's efforts to coordinate with the IRGC–QF in support of the Assad regime.[30] At the request of the IRGC–QF, Hizballah has deployed thousands of fighters into Syria in support of the Assad regime.

As recently as September 2019, Treasury took action against a large shipping network directed by and financially supporting both the IRGC–QF and Hizballah. In the past year, the IRGC–QF has moved Iranian oil worth at least hundreds of millions of USD through the network for the benefit of the Assad regime and other illicit actors. The sprawling network uses dozens of ship managers, vessels, and other facilitators and intermediaries to enable the IRGC–QF to obfuscate its involvement; to broker associated contracts, it also relies heavily on front companies and Hizballah officials (including Muhammad Qasir, designated by Treasury in November 2018 in connection with the illicit Russia-Iran oil network supporting Assad, Hizballah, and Hamas). Pursuant to E.O. 13224, Treasury identified several vessels as property in which blocked persons have an interest, and pursuant to E.O. 13224, designated 16 entities and 10 individuals, including senior IRGC–QF official and former Iranian Minister of Petroleum Rostam Qasemi, who oversees the network. Treasury Under Secretary for Terrorism and Financial Intelligence Sigal Mandelker noted that the designations demonstrated Iran's economic reliance on the terrorist groups IRGC–QF and Hizballah as financial lifelines.[31]

In July 2019, Treasury designated key Hizballah political and security figures—two members of Lebanon's Parliament and one Hizballah security official—who were leveraging their positions to facilitate Hizballah's agenda and do Iran's bidding. Noting that one of the Parliament members, Amin Sherri, has been photographed with IRGC–QF Commander Soleimani, Treasury stated that Hizballah uses its operatives in Lebanon's Parliament to bolster Iran's malign activities.[32] Also in July 2019, Treasury designated Salman Raouf Salman pursuant to E.O. 13224. Salman, a senior member of an Hizballah organization dedicated to carrying out attacks outside Lebanon, coordinated the devastating attack in 1994 against the AMIA Jewish community center in Buenos Aires, Argentina, and has been directing terrorist operations in the Western Hemisphere ever since. The designation of Salman marked over 50 Hizballah-linked designations by Treasury since 2017.[33]

Hizballah is a global terrorist organization, active in Syria, Iraq, and Yemen, and Hizballah plots have been thwarted in South America, Asia, Europe, and the United States. In June 2017 in New York, Ali Kourani and Samer El Debek were arrested and charged for alleged activities on behalf of Hizballah. Kourani conducted surveillance of potential U.S. targets, including military and law enforcement facilities in New York City, and was subsequently convicted on all eight counts, which included terrorism, sanctions, and immigration-related offenses. El Debek allegedly conducted missions in Panama to locate U.S. and

[25] *Treasury Designates Illicit Russia-Iran Oil Network Supporting the Assad Regime, Hizballah, and Hamas,* November 20, 2018, *https://home.treasury.gov/news/press-release/sm553.*

[26] *United States Disrupts Large Scale Front Company Network Transferring Hundreds of Millions of Dollars and Euros to the IRGC and Iran's Ministry of Defense,* March 26, 2019, *https://home.treasury.gov/news/press-release/sm639.*

[27] *Treasury Targets IRGC-Qods Force Financial Conduit in Iraq for Trafficking Weapons Worth Hundreds of Millions of Dollars,* June 12, 2019, *https://home.treasury.gov/news/press-release/sm706.*

[28] *Treasury Sanctions Five Individuals Tied to Iranian Plot to Assassinate the Saudi Arabian Ambassador to the United States,* October 11, 2011, *https://www.treasury.gov/press-center/press-releases/pages/tg1320.aspx.*

[29] *Hizballah,* Counterterrorism Guide, Office of the Director of National Intelligence, *https://www.dni.gov/nctc/groups/hizballah.html.*

[30] *Treasury Targets Hizballah for Supporting the Assad Regime,* August 10, 2012, *https://www.treasury.gov/press-center/press-releases/Pages/tg1676.aspx.*

[31] *Treasury Targets Wide Range of Terrorists and Their Supporters Using Enhanced Counterterrorism Sanctions Authorities,* September 10, 2019, *https://home.treasury.gov/news/press-release/sm772.*

[32] *Treasury Targets Iranian-Backed Hizballah Officials for Exploiting Lebanon's Political and Financial System,* July 9, 2019, *https://home.treasury.gov/news/press-release/sm724.*

[33] *Treasury Targets Senior Hizballah Operative for Perpetrating and Plotting Terrorist Attacks in the Western Hemisphere,* July 19, 2019, *https://home.treasury.gov/news/press-release/sm737.*

Israeli Embassies and assess the vulnerabilities of the Panama Canal and the ships that transit it.[34] [35]

According to information available to FinCEN, in early 2015, the IRGC–QF provided approximately $20 million USD to Hizballah, over half of which was to be used for ballistic missile expenses. In 2017, the CBI coordinated with Hizballah to arrange a single EUR funds transfer to a Turkish bank worth over $50 million USD.

More recently, and as noted in the previous section, in November 2018, Treasury designated nine persons involved in an international network through which Iran provided millions of barrels of oil to Syria via Russian companies, in exchange for Syria's facilitation of the movement of hundreds of millions of USD banknotes to the IRGC–QF for onward transfer to Hizballah and Hamas. Treasury noted at the time of the designations that Mohammad Amer Alchwiki, a central player in this scheme, was acting as a critical conduit for the transfer of the USD banknotes. Alchwiki worked with the Central Bank of Syria to coordinate transfers to Hizballah official Muhammad Qasir, in charge of the Hizballah unit responsible for weapons, technology, and other support transfers. In its press release, Treasury included a photo of a letter dated April 17, 2018, from Alchwiki and Qasir to a CBI official, confirming receipt of $63 million USD.[36]

Also as noted previously, in May 2018, in connection with a scheme to move millions of USD for the IRGC–QF, Treasury designated a network that included Valiollah Seif, Iran's then-governor of the CBI, Iraq-based al-Bilad Islamic Bank, and Muhammad Qasir, a Hizballah official. Treasury designated them as SDGTs pursuant to E.O. 13224 after finding that Seif had covertly funneled millions of USD on behalf of the IRGC–QF through al-Bilad Bank to support Hizballah's radical agenda.[37]

Hamas

Iran also has a history of supporting Hamas. Hamas was established in 1987 at the onset of the first Palestinian intifada. Prior to 2005, Hamas' numerous attacks on Israel included U.S. citizens as casualties. The State Department designated Hamas as an FTO in October 1997, and Treasury designated it as an SDGT pursuant to E.O. 13224 in October 2001.[38]

Iran provides Hamas with funds, weapons, and training. During periods of substantial Iran-Hamas collaboration, Iran's support to Hamas has been estimated to be as high as $300 million USD per year, but at a baseline amount, is widely assessed to be in the tens of millions per year. The Iran-Hamas relationship was forged in the 1990s as part of an attempt to disrupt the Israeli-Palestinian peace process, but in 2012, their divergent positions on Syria caused a rift. Subsequently, Iran sought to rebuild the relationship, and in October 2017, Hamas leaders restored the group's relations with Iran during a visit to Tehran.[39]

According to information available to FinCEN, in March 2015, Hamas expressed gratitude for Iran's previous financial support, and requested that Iran resume providing aid. In January 2016, Hamas officials in Gaza were awaiting monetary payments from the IRGC–QF. The Hamas officials expected the Iranian government to transfer money to the IRGC–QF in Beirut, who would then transfer it onward to them. Additionally, in 2016, Hamas had received a significant sum of IRGC–QF funding via financiers in Turkey.

In August 2019, Treasury, in partnership with the Sultanate of Oman, designated financial facilitators who funneled tens of millions of USD between the IRGC–QF and Hamas's operational arm, the Izz-Al-Din Al-Qassam Brigades, for terrorist attacks originating from Gaza. The Izz-Al-Din Al-Qassam Brigades is a designated FTO and SDGT. At the center of the scheme uncovered by Treasury and Oman was Mohammad Sarur, a Lebanon-based financial operative in charge of all financial transfers between the IRGC–QF and the Izz-Al-Din Al-Qassam Brigades. Sarur was a middle-man between the IRGC–QF and Hamas and worked with Hizballah operatives to ensure the Izz-Al-Din Al-Qassam Brigades received funds. The IRGC–QF transferred over $200 million USD to the Izz-Al-Din Al-Qassam Brigades in the past four years.[40]

In September 2019, in an action targeting a wide range of terrorists and their supporters using enhanced counterterrorism sanctions authorities, Treasury designated two Iran-linked Hamas officials. Pursuant to the amended counterterrorism E.O., E.O. 13224, Treasury designated Turkey-based Redin Exchange and its Deputy Head, Ismael Tash. Since at least 2017, Tash has had contact with a money transfer channel managed by Mohammad Sarur that transferred IRGC–QF money to Hamas; as of January 2019, Tash was a key player in many Iran-Hamas financial transfers. Treasury also designated Zaher Jabarin, the Turkey-based head of Hamas' Finance Office. Jabarin has overseen the transfer of hundreds of thousands of USD in the West Bank to finance Hamas' terrorist activities; he has also served as a primary interlocutor between Hamas and the IRGC–QF.[41]

Taliban

Iran seeks influence in Afghanistan in a number of ways, including by offering economic assistance and engaging the central government—but also by arming Taliban fighters and supporting pro-Iranian groups. In October 2010, then-President Hamid Karzai admitted that Iran was providing about $2 million USD annually in cash payments to his government.[42] Treasury designated the Taliban as an SDGT in 2002.

In October 2018, the seven member nations of the Terrorist Financing Targeting Center (TFTC),[43] designated nine Taliban-associated individuals, including those facilitating Iranian support to bolster the Taliban. The Secretary described Iran's provision of support to the Taliban as yet another example of its support for terrorism, and its utter disregard for United Nations Security Council Resolutions (UNSCRs) and other international norms. Treasury noted that the action's inclusion of IRGC–QF members supporting Taliban elements highlighted the scope of Iran's regionally destabilizing behavior.

[34] *Bronx Man and Michigan Man Arrested for Terrorist Activities On Behalf Of Hizballah's Islamic Jihad Organization,* June 8, 2017, *https://www.justice.gov/usao-sdny/pr/bronx-man-and-michigan-man-arrested-terrorist-activities-behalf-hizballah-s-islamic.*

[35] *Ali Kourani Convicted in Manhattan Federal Court for Covert Terrorist Activities on Behalf of Hizballah's Islamic Jihad Organization,* May 17, 2019, *https://www.justice.gov/opa/pr/ali-kourani-convicted-manhattan-federal-court-terrorist-activities-behalf-hizballah-s.*

[36] *Treasury Designates Illicit Russia-Iran Oil Network Supporting the Assad Regime, Hizballah, and Hamas,* November 20, 2018, *https://home.treasury.gov/news/press-release/sm553.*

[37] *Treasury Targets Iran's Central Bank Governor and an Iraqi Bank Moving Millions of Dollars for IRGC-Qods Force,* May 15, 2018, *https://home.treasury.gov/news/press-release/sm0385.*

[38] *Country Reports on Terrorism 2016,* U.S. Department of State, Chapter 3: State Sponsors of Terrorism, Iran, Chapter 6, Foreign Terrorist Organizations, Hamas.

[39] *Iran's Foreign and Defense Policies,* Congressional Research Service, R44017, Version 56, Updated October 9, 2018.

[40] *Treasury Targets Facilitators Moving Millions to HAMAS in Gaza,* August 29, 2019, *https://home.treasury.gov/news/press-release/sm761.*

[41] *Treasury Targets Wide Range of Terrorists and Their Supporters Using Enhanced Counterterrorism Sanctions Authorities,* September 10, 2019, *https://home.treasury.gov/news/press-release/sm772.*

[42] *Iran's Foreign and Defense Policies,* Congressional Research Service, R44017, Version 70, Updated July 23, 2019.

[43] The seven TFTC member states are the U.S., Saudi Arabia, Bahrain, Kuwait, Oman, Qatar, and the UAE.

Among those designated were Mohammad Ebrahim Owhadi, an IRGC–QF officer, and Abdullah Samad Faroqui, the Taliban Deputy Shadow Governor for Herat Province. In 2017, Owhadi and Faroqui reached an agreement for the IRGC–QF's provision of military and financial assistance to Faroqui, in exchange for Faroqui's forces attacking the Afghan government in Herat. Also designated were Esma'il Razavi, who was in charge of the training center at the IRGC–QF base in Birjand, Iran, which as of 2014, provided training, intelligence, and weapons to Taliban forces in Farah, Ghor, Badhis, and Helmand Provinces, Afghanistan. In 2008, as the senior IRGC–QF official in Birjand, Razavi's base supported anti-coalition militants in Farah and Herat. Also designated by the TFTC were Naim Barich, previously Treasury- and UN-sanctioned, who as of late 2017 was the Taliban Shadow Minister of Foreign Affairs managing Taliban relations with Iran, and Sadr Ibrahim, the leader of the Taliban's Military Commission, whom Iranian officials agreed to provide with financial and training support in order to build the Taliban's tactical and combat capabilities.[44]

d. Entities Involved in the Proliferation of WMD or Missiles

Under UNSCR 2231 (2015), which endorsed the JCPOA, the sale, supply, or transfer to Iran of Nuclear Suppliers Group (NSG)[45]-controlled items requires advance approval by the UNSC. Despite this, in July 2019, Treasury identified and acted against a network of front companies and agents involved in procuring sensitive materials—including NSG-controlled materials—without UNSC approval for sanctioned elements of Iran's nuclear program. Treasury designated seven entities and five individuals in Iran, China, and Belgium, for acting as a procurement network for Iran's Centrifuge Technology Company, which plays a crucial role in Iran's uranium enrichment through the production of centrifuges for Atomic Energy Organization of Iran facilities.[46]

Additionally, in August 2019, Treasury designated two Iranian regime-linked networks pursuant to E.O. 13382 for engaging in covert procurement activities benefiting multiple Iranian military organizations. One network has used a Hong Kong-based front company to evade U.S. and international sanctions and procure tens of millions of dollars' worth of U.S. technology and electronic components on behalf of the IRGC and Iran's missile program. The other network has procured NSG-controlled aluminum alloy products on behalf of MODAFL subsidiaries.[47]

Iran's ongoing pursuit of ballistic missile technology is well known. In 2018, Iran conducted nine ballistic missile tests in defiance of UNSCR 2231 (2015), including the launch of short range ballistic missiles in September and October 2018, which were inconsistent with paragraph 3 of Annex B of UNSCR 2231.[48] The U.S. Secretary of State described Iran's test-firing of a medium-range ballistic missile capable of carrying multiple warheads in December 2018 as another violation of UNSCR 2231.[49] In July 2017, Iran tested a Simorgh space launch vehicle, which the United States, France, Germany, and the United Kingdom all assessed to have used technology similar to that of intercontinental ballistic missiles.[50] In January 2017, Iran launched a medium-range missile able to carry a payload greater than 500 kilograms in excess of 300 kilometers, making it inherently capable of delivering a nuclear explosive device. In 2016, Iran unveiled two short-range ballistic missiles and announced that it was pursuing long-range precision-guided missiles.[51]

In January 2018, two Iranian nationals tried to buy Kh-31 missile components in Kiev, Ukraine, which would have been a violation of the UN arms embargo on Iran. Ukraine's security service detained the men while they were in possession of the missile parts and technical documents on their use. Ukraine subsequently deported the men, one of whom was a military attaché at Iran's Embassy in Kiev.[52]

According to information available to FinCEN, Iran's Shahid Bakeri Industrial Group (SBIG) and Shahid Hemmat Industrial Group (SHIG), respectively its solid and liquid propellant ballistic missile producers, utilize foreign entities and networks to procure missile-related materials and technology and disguise their involvement in the process. SBIG and SHIG are listed in the annex to E.O. 13382, which targets proliferators of WMD and their supporters. Among the targets in Treasury's August 2019 designation action was the Iranian firm Ebtekar Sanat Ilya, which helped procure more than one million dollars' worth of export-controlled, military-grade electronic components for Iranian military clients—including both SBIG and SHIG.

In February 2017, Treasury designated entities and individuals that were part of the Abdollah Asgharzadeh network in connection with their procurement of dual-use and other goods on behalf of organizations involved in Iran's ballistic missile program. The network coordinated procurement through intermediary companies that obfuscated the true end-user of the goods, and relied on the assistance of trusted brokers based in China.[53]

Factor 2: The Extent to Which That Jurisdiction Is Characterized by High Levels of Official or Institutional Corruption

The endemic corruption of Iran's government is well-known. According to information available to FinCEN, in late 2017, IRGC officials were aware of corruption and mismanagement at an IRGC economic development firm. The officials estimated the cost of the corruption to be approximately $5.5 billion USD—a figure which represented losses, debts, and funds required for a capital injection to facilitate the firm's dissolution.

Also according to information available to FinCEN, as of mid-January 2018, after hearing complaints about corruption in the armed forces' financial institutions, Iranian Supreme Leader Ali Hoseini Khamenei issued a directive requiring Iran's armed forces to sell the private companies they owned. However, because Khamenei permitted

[44] *Treasury and the Terrorist Financing Targeting Center Partners Sanction Taliban Facilitators and their Iranian Supporters,* October 23, 2018, *https://home.treasury.gov/news/press-release/sm532.*

[45] The NSG is a multinational export control regime that seeks to prevent nuclear proliferation by controlling the export of materials, equipment, and technology that can be used to manufacture nuclear weapons.

[46] *Treasury Sanctions Global Iranian Nuclear Enrichment Network,* July 18, 2019, *https://home.treasury.gov/news/press-release/sm736.*

[47] *Treasury Targets Procurement Networks Supporting Iran's Missile Proliferation Programs,* August 28, 2019, *https://home.treasury.gov/news/press-release/sm759.*

[48] *Letter from the Permanent Representative of Israel to the UN,* November 23, 2018.

[49] *Pompeo Condemns Iran Missile Test,* Reuters, December 1, 2018.

[50] *Letter from the Permanent Mission of the Federal Republic of Germany to the UN, United Kingdom Mission to the UN, and the Mission Permanente De La France Aupres Des Nations Unies to H.E. Mr. Ma Zhaoxu, Ambassador, Permanent Representative of the People's Republic of China to the UN,* November 20, 2018.

[51] *Iran's Missile Proliferation: A Conversation with Special Envoy Brian Hoo*k, Hudson Institute, September 19, 2018.

[52] *Busted: Ukraine Catches Iranian Military Attaché Trying to Smuggle KH–31 Parts out of Kiev,* The National Interest, July 2, 2019.

[53] *Treasury Sanctions Supporters of Iran's Ballistic Missile Program and Iran's Islamic Revolutionary Guard Corps-Qods Force,* February 23, 2017, *https://www.treasury.gov/press-center/press-releases/Pages/as0004.aspx.*

the armed forces to use revenue from the sales to then purchase shares in the same companies, the directive appeared to be a mere symbolic gesture to placate public pressure, not a genuine effort to lessen the IRGC's role in the economy or curb corruption.

In October 2018, Treasury designated an Iran-based network comprised of businesses providing financial support to the Basij Resistance Force, a paramilitary force subordinate to the IRGC. As noted at the time of the designation, among other malign activities, the IRGC Basij militia recruits, trains, and deploys child soldiers to fight in IRGC-fueled conflicts across the region. The Basij also employs shell companies and other measures to mask its ownership and control over a variety of multibillion-dollar business interests in Iran's automotive, mining, metals, and banking industries.[54]

In June 2019, Treasury designated Iran's largest and most profitable petrochemical holding group, Persian Gulf Petrochemical Industries Company, for providing financial support to Khatam al-Anbiya Construction Headquarters, the engineering arm of the IRGC. Treasury noted that the IRGC and its major holdings have a dominant presence in Iran's commercial and financial sectors, maintaining extensive economic interests in the defense, construction, aviation, oil, banking, metal, automobile, and mining industries.[55]

Factor 3: The Substance and Quality of Administration of the Bank Supervisory and Counter-Money Laundering Laws of That Jurisdiction

For more than a decade, the international community has been concerned about the deficiencies in Iran's anti-money laundering/countering the financing of terrorism (AML/CFT) program. As far back as October 11, 2007, the Financial Action Task Force (FATF) issued a statement on Iran's lack of a comprehensive AML/CFT regime, noting it represented a significant vulnerability in the international financial system. The FATF called upon Iran to urgently address its AML/CFT deficiencies, and advised financial institutions to apply enhanced due diligence.[56] In February 2009, the FATF elevated its call for enhanced due diligence by calling upon its members and urging all jurisdictions to apply effective counter-measures to protect their financial sectors from money laundering and terrorist financing risks emanating from Iran.

In June 2016, due to Iran's adoption of, and high-level political commitment to, an Action Plan to address its strategic AML/CFT deficiencies, the FATF agreed to suspend counter-measures for 12 months in order to monitor Iran's progress in implementing its Action Plan. At the same time however, the FATF expressed its continuing concern with the terrorist financing risk emanating from Iran and the threat this posed to the international financial system, and called for financial institutions to continue applying enhanced due diligence with respect to Iran-related business relationships and transactions.[57] The FATF issued similar statements between October 2016 and June 2017, and in October 2018 and February 2019 identified specific types of enhanced due diligence measures to be applied against Iran-related business relationships and transactions.[58]

In its June 2019 and October 2019 Public Statements, the FATF noted that Iran's Action Plan had expired in January 2018 and that major items remained outstanding, including (1) adequately criminalizing terrorist financing, including by removing the exemption for designated groups ''attempting to end foreign occupation, colonialism, and racism;'' (2) identifying and freezing terrorist assets in line with the relevant UNSCRs; (3) ensuring an adequate and enforceable customer due diligence regime; (4) clarifying that the submission of suspicious transaction reports for attempted terrorist financing-related transactions is covered under Iran's legal framework; (5) demonstrating how authorities are identifying and sanctioning unlicensed money/value transfer service providers; (6) ratifying and implementing the Palermo and Terrorist Financing Conventions and clarifying the capability to provide mutual legal assistance; and (7) ensuring that financial institutions verify that wire transfers contain complete originator and beneficiary information.[59] [60]

Due to these critical deficiencies, in June 2019, the FATF decided to call upon its members and urge all jurisdictions to increase supervisory examination for branches and subsidiaries of financial institutions based in Iran.[61] In October 2019, the FATF decided to call upon its members and urge all jurisdictions to introduce enhanced relevant reporting mechanisms or systematic reporting of financial transactions; and require increased external audit requirements for financial groups with respect to any of their branches and subsidiaries located in Iran.[62] The FATF followed this new requirement with a warning stating that if before February 2020, Iran does not enact the Palermo and Terrorist Financing Conventions in line with the FATF Standards, then the FATF will fully lift the suspension of counter-measures and call on its members and urge all jurisdictions to apply effective counter-measures.[63]

A number of public statements from senior Iranian government officials suggest that Iran has no real intention of adhering to international norms, including the FATF standards. On March 8, 2019, Gholamreza Mesbahi Moghaddam, senior member of Iran's Expediency Council, the highest-level political institution after the office of the Supreme Leader, said ''Passing CFT and Palermo means giving away our only remaining mechanism to bypass U.S. sanctions which is to register shell corporations in Iran and other countries to do international trade deals.'' [64] On February 1, 2019, former Iranian Defense Minister Brigadier General Ahmad Vahidi, also an Expediency Council member, said, the [FATF] recommendations threaten Iran's economy and it is a framework adopted by the global arrogance to impose restrictions on Iran and pursue the

[54] *Treasury Designates Vast Financial Network Supporting Iranian Paramilitary Force That Recruits and Trains Child Soldier*s, October 16, 2018, *https://home.treasury.gov/news/press-release/sm524.*

[55] *Treasury Sanctions Iran's Largest Petrochemical Holding Group and Vast Network of Subsidiaries and Sales Agents,* June 7, 2019, *https://home.treasury.gov/news/press-release/sm703.*

[56] *FATF Statement on Iran,* 11 October 2007, *https://www.fincen.gov/sites/default/files/shared/FATFOct2007.pdf.*

[57] *Public Statement—24 June 2016, https://www.fatf-gafi.org/publications/high-riskandnon-cooperativejurisdictions/documents/public-statement-june-2016.html.*

[58] *Public Statement—23 June 2017, https://www.fatf-gafi.org/publications/high-riskandnon-cooperativejurisdictions/documents/public-statement-june-2017.html.*

[59] *Public Statement—June 2019, https://www.fatf-gafi.org/publications/high-risk-and-other-monitored-jurisdictions/documents/public-statement-june-2019.html.*

[60] *Public Statement—October 2019, https://www.fatf-gafi.org/publications/high-risk-and-other-monitored-jurisdictions/documents/public-statement-october-2019.html.*

[61] *Public Statement—June 2019, https://www.fatf-gafi.org/publications/high-risk-and-other-monitored-jurisdictions/documents/public-statement-june-2019.html.*

[62] *Public Statement—October 2019, https://www.fatf-gafi.org/publications/high-risk-and-other-monitored-jurisdictions/documents/public-statement-october-2019.html.*

[63] *Id.*

[64] *Mesbahi Moghaddam: We Will Not Stop Evading Sanctions,* Iran International, March 9, 2019, *https://iranintl.com/en/iran/mesbahi-moghaddam-we-will-not-stop-evading-sanctions.*

sanctions re-imposed against Tehran in smarter ways.'' [65] On September 9, 2018, Ayatollah Ahmad Jannati, secretary of Iran's powerful Guardian Council, said, ''I've studied both the Persian and English versions and I soon came to the conclusion that they want to give our financial and banking information to the enemy. They want us to sanction ourselves. They want us to sanction the individuals and institutions that the enemy disagrees with. They want us to sanction the [IRGC], revolutionary institutions, and individuals.'' [66]

Factor 4: Whether the United States Has a Mutual Legal Assistance Treaty (MLAT) With That Jurisdiction, and the Experience of U.S. Law Enforcement Officials and Regulatory Officials in Obtaining Information About Transactions Originating in or Routed Through Such Jurisdiction

The United States and Iran have not had a substantive relationship since the hostage-taking of U.S. Embassy personnel by Iranians in November 1979, and subsequent severing of diplomatic relations in April 1980.

MLATs facilitate the exchange of information and financial records with treaty partners in criminal and related matters. The State Department negotiates MLATs in cooperation with the U.S. Department of Justice. As of the date of this document, no MLAT is in force with Iran. Additionally, the Egmont Group is an international organization through which many countries' financial intelligence units (FIUs) share invaluable financial and other information useful in law enforcement and regulatory investigations. As the U.S. FIU, FinCEN is the U.S. representative to the Egmont Group. No Iranian government entity is, nor ever has been, a member of the Egmont Group.

Given the lack of any cooperative relationship generally, as well as Iran's inability to share information with the United States via an MLAT or the Egmont Group, the level of U.S.-Iran cooperation on AML/CFT matters is nonexistent. As a result, U.S. law enforcement and regulatory officials have an extremely limited ability to obtain information about transactions originating in or routed through Iran.

VI. Considerations in Selecting the Fifth Special Measure

Below is a discussion of the relevant criteria FinCEN considered in selecting a prohibition under the fifth special measure with respect to Iran, after having completed the required interagency consultations with Chairman of the Board of Governors of the Federal Reserve System, the Secretary of State, the Securities and Exchange Commission, the Commodity Futures Trading Commission, and the National Credit Union Administration Board in accordance with 31 U.S.C. 5318A(a)(4)(A) and the Secretary of State, the Attorney General, and the Chairman of the Board of Governors of the Federal Reserve System in accordance with 31 U.S.C. 5318A(b)(5).

Whether Similar Action Has Been or Will Be Taken by Other Nations or Multilateral Groups Against Iran

FinCEN notes that two Iranian banks are currently designated by the European Union as entities subject to an asset freeze and prohibition to make funds available: Ansar Bank and Mehr Bank. FinCEN is unaware of any other nation or multilateral group that has prohibited or placed conditions on Iranian banks' correspondent banking relationships, or has plans to do so. However, as noted previously, in October 2019, the FATF decided to call upon its members and urge all jurisdictions to introduce enhanced relevant reporting mechanisms or systematic reporting of financial transactions; and require increased external audit requirements for financial groups with respect to any of their branches and subsidiaries located in Iran. The FATF followed this new requirement with a warning stating that if before February 2020, Iran does not enact the Palermo and Terrorist Financing Conventions in line with the FATF Standards, then the FATF will fully lift the suspension of counter-measures and call on its members and urge all jurisdictions to apply effective counter-measures.[67] Regardless of the FATF's future actions, FinCEN assesses that the correspondent account prohibition under the fifth special measure is necessary to ensure the security of the U.S. financial system and combat Iran's malign and illicit activities, including its support for international terrorism.

Whether the Imposition of the Fifth Special Measure Would Create a Significant Competitive Disadvantage, Including Any Undue Cost or Burden Associated With Compliance, for Financial Institutions Organized or Licensed in the United States

Existing sanctions programs on Iran administered by OFAC generally prohibit the exportation, reexportation, sale, or supply, directly or indirectly, from the United States, or by a U.S. person, wherever located, of any goods, technology, or services to Iran. As a result, U.S. financial institutions are already broadly prohibited under existing OFAC sanctions from opening or maintaining correspondent accounts for, or on behalf of, Iranian financial institutions, or conducting any financial transactions involving Iranian financial institutions unless exempt from U.S. sanctions or authorized by OFAC. In addition, as of late September 2019, 24 Iranian financial institutions had been designated under E.O. 13224, ten Iranian financial institutions under E.O. 13382, one Iranian financial institution under E.O. 13846, and one Iranian financial institution under E.O. 13553. Secondary sanctions apply to certain transactions with each of these Iranian banks.[68] FinCEN assesses that secondary sanctions already deter most foreign financial institutions from doing business with targeted Iranian financial institutions, and the correspondent account prohibition under the fifth special measure will create no competitive disadvantage for U.S. financial institutions.

The Extent to Which the Action or Timing of the Action Will Have a Significant Adverse Systemic Impact on the International Payment, Clearance, and Settlement System, or on Legitimate Business Activities of Iranian Financial Institutions

FinCEN has no information indicating that Iranian financial institutions are major participants in the international payment system or that they are relied upon by the international banking community for clearance or settlement services. Further, as of mid-November 2018, the Society for Worldwide Interbank Financial Telecommunication (SWIFT) had disconnected designated Iranian financial institutions, including the CBI, from its financial messaging service. Lastly, FinCEN assesses that most Iranian payments are made using currencies other than USD due to a long

[65] *Iran Warns Europe to Avoid Tying Up INSTEX to FATF,* February 5, 2019, *https://en.farsnews.com/newstext.aspx?nn=13971116000195.*

[66] *Iran Faces Challenges in Implementing Its FATF Action Plan,* October 26, 2016, *https://www.washingtoninstitute.org/policy-analysis/view/iran-faces-challenges-in-implementing-its-fatf-action-plan; https://www.aryanews.com/news/20160909150648732* (original Farsi-language article)

[67] *Public Statement—June 2019, https://www.fatf-gafi.org/publications/high-risk-and-other-monitored-jurisdictions/documents/public-statement-june-2019.html.*

[68] Secondary sanctions generally are directed toward non-U.S. persons for specified conduct involving Iran that occurs entirely outside of U.S. jurisdiction, according to OFAC's website.

history of U.S. sanctions and actions targeting Iran. Thus, there is no reason to conclude that the imposition of a prohibition under the fifth special measure against the jurisdiction of Iran will have an adverse systemic impact on the international payment, clearance, and settlement system. FinCEN also considered the extent to which this action could have an impact on the legitimate business activities of Iranian financial institutions, and has concluded that the need to protect the U.S. financial system from Iran strongly outweighs any such impact.

The Effect of the Action on U.S. National Security and Foreign Policy

FinCEN assesses that prohibiting covered financial institutions from maintaining correspondent accounts for Iranian financial institutions, and preventing Iranian financial institutions' indirect access to U.S. correspondent accounts, will enhance national security. The action serves as a measure to further prevent illicit Iranian actors from accessing the U.S. financial system. It will further the U.S. national security and foreign policy goals of thwarting and exposing illicit Iranian financial activity. Further, to the extent that other nations, particularly those that are strong U.S. trading partners, choose to transact with Iran, there is a greater risk of indirect activity occurring between U.S. financial institutions and Iran. Imposition of the fifth special measure will impose a higher standard of due diligence on U.S. financial institutions in their engagement with non-U.S. financial institutions.

Consideration of Alternative Special Measures

As an alternative to a prohibition under the fifth special measure on the opening or maintenance of correspondent accounts in the United States for or on behalf of Iranian financial institutions, and the use of foreign financial institutions' correspondent accounts at covered U.S. financial institutions to process transactions involving Iranian financial institutions, FinCEN considered special measures one through four, which impose additional recordkeeping, information collection, and reporting requirements on covered U.S. financial institutions. Under special measure five, FinCEN also considered imposing conditions on the opening or maintaining of correspondent accounts as an alternative to a prohibition on the opening or maintaining of correspondent accounts.

Given the nature of the illicit finance threat, including the terrorist-finance threat, that the jurisdiction of Iran poses to the United States and the U.S. financial system, Iran's well-documented history of obscuring the true nature of its illicit finance activities, and Iran's apparent disregard of regulatory reform and enforcement measures, as evidenced by the FATF's longstanding criticisms of its inadequate AML/CFT program, FinCEN assesses that any condition, additional recordkeeping, information collection, or reporting requirement would be insufficient to guard against the risks posed by covered financial institutions that process Iran-related transactions designed to obscure the transactions' true purpose, and that are ultimately for the benefit of illicit Iranian actors or activities. Special measures one through four and the imposition of conditions under special measure five would therefore fail to prevent Iran from accessing the U.S. financial system, either directly or indirectly, through the correspondent accounts at U.S. financial institutions. FinCEN assesses that a prohibition under the fifth special measure is the only special measure that can adequately protect the U.S. financial system from the illicit financial risk posed by Iran.

VII. Section-by-Section Analysis for the Imposition of a Prohibition Under the Fifth Special Measure

Section 1010.661(a)—Definitions

1. Iranian Financial Institution

The final rule defines ''Iranian financial institution'' as any foreign financial institution, as defined at 31 CFR 1010.605(f), organized under Iranian law wherever located, including any agency, branch, office, or subsidiary of such a financial institution operating in any jurisdiction, and any branch or office within Iran of any foreign financial institution.

2. Correspondent Account

The final rule defines ''correspondent account'' to have the same meaning as the definition contained in 31 CFR 1010.605(c). In the case of a U.S. depository institution, this broad definition includes most types of banking relationships between a U.S. depository institution and a foreign bank that are established to provide regular services, dealings, and other financial transactions, including a demand deposit, savings deposit, or other transaction or asset account, and a credit account or other extension of credit. FinCEN is using the same definition of ''account'' for purposes of this final rule as was established for depository institutions in the final rule implementing the provisions of Section 312 of the USA PATRIOT Act requiring enhanced due diligence for correspondent accounts maintained for certain foreign banks.[69] Under this definition, ''payable-through accounts'' are a type of correspondent account. In the case of securities broker-dealers, futures commission merchants, introducing brokers-commodities, and investment companies that are open-end companies (''mutual funds''), FinCEN is also using the same definition of ''account'' for purposes of this final rule as was established for these entities in the final rule implementing the provisions of Section 312 of the USA PATRIOT Act requiring enhanced due diligence for correspondent accounts maintained for certain foreign banks.[70]

3. Covered Financial Institution

The final rule defines ''covered financial institution'' with the same definition used in the final rule implementing the provisions of Section 312 of the USA PATRIOT Act, which in general includes the following:

- An insured bank (as defined in section 3(h) of the Federal Deposit Insurance Act (12 U.S.C. 1813(h)));
- a commercial bank;
- an agency or branch of a foreign bank in the United States;
- a Federally-insured credit union;
- a savings association;
- a corporation acting under section 25A of the Federal Reserve Act (12 U.S.C. 611);
- a trust bank or trust company;
- a broker or dealer in securities;
- a futures commission merchant or an introducing broker-commodities; and
- a mutual fund.

4. Foreign bank

The final rule defines ''foreign bank'' to mean a bank organized under foreign law, or an agency, branch, or office located outside the United States of a bank. The term does not include an agent, agency, branch, or office within the United States of a bank organized under foreign law. This is consistent with the definition of ''foreign bank'' under 31 CFR 1010.100.

5. Subsidiary

The final rule defines ''subsidiary'' to mean a company of which more than 50 percent of the voting stock or analogous equity interest is owned by another company.

[69] *See* 31 CFR 1010.605(c)(2)(i).

[70] *See* 31 CFR 1010.605(c)(2)(ii)–(iv).

Section 1010.661(b)—Prohibition on Accounts and Due Diligence Requirements for Covered Financial Institutions

1. Prohibitions on Opening or Maintaining Correspondent Accounts

Section 1010.661(b)(1) and (2) of this final rule prohibits covered financial institutions from opening or maintaining in the United States correspondent accounts for, or on behalf of, Iranian financial institutions, unless such account is authorized by OFAC. In addition, under § 1010.661(b)(2) of this final rule, a covered financial institution shall take reasonable steps to not process a transaction for the correspondent account of a foreign bank in the United States if such a transaction involves an Iranian financial institution, unless such transactions or payments are authorized by OFAC.

Section 1010.661(b)(2) requires covered financial institutions to take reasonable steps to not process transactions for the correspondent accounts of foreign banks in the United States involving Iranian financial institutions that are prohibited transactions.

The general licenses (*i.e.,* those of general applicability) issued pursuant to the Iranian Transactions Sanctions Regulations (ITSR) 31 CFR part 560 are either published in the ITSR or available on OFAC's website: *http://www.treasury.gov/resource-center/sanctions/programs/pages/iran.aspx.* To ensure that those permitted activities are available as a practical matter, correspondent accounts covered by the exception may continue to be used to conduct those permitted transactions. Such reasonable steps are described in § 1010.661(b)(3), which sets forth the special due diligence requirements a covered financial institution will be required to take when it knows or has reason to believe that a transaction involves an Iranian financial institution.

2. Special Due Diligence for Correspondent Accounts

As a corollary to the prohibition set forth in § 1010.661(b)(1) and (2), § 1010.661(b)(3) of the final rule will require covered financial institutions to apply to all of their foreign correspondent accounts special due diligence that is reasonably designed to guard against such accounts being used to process prohibited transactions involving Iranian financial institutions. As part of that special due diligence, covered financial institutions are required to notify those foreign correspondent account holders that the covered financial institutions know, or have reason to believe, provide services to Iranian financial institutions, that such correspondent institutions may not provide the Iranian financial institutions with access to the correspondent accounts maintained at the covered financial institutions to process prohibited transactions. A covered financial institution may satisfy this notification requirement using the following notice:

> Notice: Pursuant to U.S. regulations issued under Section 311 of the USA PATRIOT Act, see 31 CFR 1010.661, we are prohibited from opening or maintaining in the United States a correspondent account for, or on behalf of, any Iranian financial institution. The regulations also require us to notify you that you may not provide an Iranian financial institution, including any of its agencies, branches, offices, or subsidiaries, with access to the correspondent account you hold at our financial institution to process transactions that are prohibited, and not authorized or exempt, pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), any regulation, order directive or license issued pursuant thereto, or any other sanctions program administered by the Department of the Treasury's Office of Foreign Asset Control (''prohibited transactions''). If we become aware that the correspondent account you hold at our financial institution has processed any prohibited transactions involving Iranian financial institutions, including any agencies, branches, offices, or subsidiaries thereof, we will be required to take appropriate steps to prevent such access, including terminating your account.

The purpose of the notice requirement is to aid cooperation with correspondent account holders in preventing transactions involving Iranian financial institutions from accessing the U.S. financial system. FinCEN does not require or expect a covered financial institution to obtain a certification from any of its correspondent account holders that access will not be provided to comply with this notice requirement. Methods of compliance with the notice requirement could include, for example, transmitting a notice by mail, fax, or email. The notice should be transmitted whenever a covered financial institution knows or has reason to believe that a foreign correspondent account holder provides services to an Iranian financial institution.

Special due diligence also includes implementing risk-based procedures designed to identify any use of correspondent accounts to process transactions involving Iranian financial institutions. A covered financial institution is expected to apply an appropriate screening mechanism to identify a funds transfer order that on its face listed an Iranian financial institution as originator or beneficiary, or otherwise referenced an Iranian financial institution in a manner detectable under the financial institution's normal screening mechanisms. An appropriate screening mechanism could be the mechanisms used by a covered financial institution to comply with various legal requirements, such as the commercially available software programs used to comply with the economic sanctions programs administered by OFAC.

3. Recordkeeping and Reporting

Section 1010.661(b)(4) of this rule clarifies that paragraph (b) of the rule does not impose any reporting requirement upon any covered financial institution that is not otherwise required by applicable law or regulation. A covered financial institution must, however, document its compliance with the notification requirement under § 1010.661(b)(3)(i)(A).

VIII. Paperwork Reduction Act

The collection of information contained in this final rule is being submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), and has been assigned OMB Control Number 1506–0074. 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 OMB control number.

Description of Affected Financial Institutions: Banks, broker-dealers in securities, futures commission merchants, introducing brokers-commodities, and mutual funds.

Estimated Number of Affected Financial Institutions: 23,615.[71]

Estimated Average Annual Burden in Hours per Affected Financial Institution: The estimated average burden associated with the collection of information in this final rule is two

[71] This number is a total of: (1) The institutions represented in the most recent reports of the following regulators: the NCUA, who reported 5,375 institutions as of December 31, 2018 in its *Quarterly Credit Union Data Summary: 2018 Q4,* and the FDIC, who reported 5,358 FDIC-insured institutions in its *Key Statistics* as of April 25, 2019; (2) a March 2017 Government Accountability Office *Report PRIVATE DEPOSIT INSURANCE: Credit Unions Largely Complied with Disclosure Rules, but Rules Should Be Clarified,* that indicated that approximately 125 credit unions were insured privately; (3) 1,130 introducing brokers and 64 futures commodities merchants reported by the National Futures Association on its website as of March 31, 2019; (4) 3,607 securities firms as of December 31, 2018 as reported by FINRA on its website; and, (5) 7,956 U.S. mutual funds, according to the *2018 Investment Company Fact Book* published by the Investment Company Institute.

hours per affected financial institution.[72]

Estimated Total Annual Burden: 47,230 hours.

List of Subjects in 31 CFR Part 1010

Administrative practice and procedure, Banks and banking, Brokers, Counter-money laundering, Counter-terrorism, Foreign banking.

Authority and Issuance

For the reasons set forth in the preamble, Part 1010, chapter X of title 31 of the Code of Federal Regulations, is amended as follows:

PART 1010—GENERAL PROVISIONS

■ 1. The authority citation for Part 1010 continues to read as follows:

Authority: 12 U.S.C. 1829b and 1951–1959; 31 U.S.C. 5311–5314, 5316–5332; Title III, sec. 314, Pub. L. 107–56, 115 Stat. 307; sec. 701, Pub. L. 114–74, 129 Stat. 599.

■ 2. Add § 1010.661 to read as follows:

§ 1010.661 Special measures against Iran.

(a) *Definitions.* For purposes of this section:

(1) *Iranian financial institution* means any foreign financial institution, as defined at § 1010.605(f), organized under Iranian law wherever located, including any agency, branch, office, or subsidiary of such a financial institution operating in any jurisdiction, and any branch or office within Iran of any foreign financial institution.

(2) *Correspondent account* has the same meaning as provided in § 1010.605(c).

(3) *Covered financial institution* has the same meaning as provided in § 1010.605(e)(1).

(4) *Foreign bank* has the same meaning as provided in § 1010.100.

(5) *Subsidiary* means a company of which more than 50 percent of the voting stock or analogous equity interest is owned by another company.

(b) *Prohibition on accounts and due diligence requirements for covered financial institutions*—(1) *Opening or maintaining correspondent accounts for Iranian financial institutions.* A covered financial institution shall not open or maintain in the United States a correspondent account for, or on behalf of, an Iranian financial institution, unless such account is authorized by United States Department of the Treasury's Office of Foreign Assets Control (OFAC).

Note 1 to paragraph (b)(1): *Note that covered financial institutions should block and report to OFAC any accounts that are blocked pursuant to any OFAC sanctions authority and therefore should continue to maintain such accounts in accordance with the Reporting Procedures and Penalties Regulations, 31 CFR part 501.*

(2) *Prohibition on use of correspondent accounts.* A covered financial institution shall take reasonable steps to not process a transaction for the correspondent account of a foreign bank in the United States if such a transaction involves an Iranian financial institution, unless the transaction is authorized by, exempt from, or not prohibited under the International Emergency Economic Powers Act (IEEPA) (50 U.S.C. 1701 *et seq.*), any regulation, order, directive, or license issued pursuant thereto, or any other sanctions program administered by the Department of the Treasury's Office of Foreign Asset Control.

(3) *Special due diligence of correspondent accounts to prohibit use.* (i) A covered financial institution shall apply special due diligence to the correspondent accounts of a foreign bank that is reasonably designed to guard against their use to process transactions involving Iranian financial institutions that are prohibited, and not authorized or exempt, pursuant to the IEEPA, any regulation, order, directive, or license issued pursuant thereto, or any other sanctions program administered by the Department of the Treasury's Office of Foreign Asset Control (''prohibited transactions''). At a minimum, that special due diligence must include:

(A) Notifying those foreign correspondent account holders that the covered financial institution knows or has reason to believe the correspondent account is being used to process transactions involving Iranian financial institutions that such prohibited transactions may not take place; and

(B) Taking reasonable steps to identify any use of its foreign correspondent accounts for prohibited transactions involving Iranian financial institutions, to the extent that such use can be determined from transactional records maintained in the covered financial institution's normal course of business.

(ii) A covered financial institution shall take a risk-based approach when deciding what, if any, other due diligence measures it reasonably must adopt to guard against the use of its foreign correspondent accounts to process prohibited transactions involving Iranian financial institutions.

(iii) A covered financial institution that knows or has reason to believe that a foreign bank's correspondent account has been or is being used to process prohibited transactions involving Iranian financial institutions shall take all appropriate steps to further investigate and prevent such access, including the notification of its correspondent account holder under paragraph (b)(3)(i)(A) of this section and, where necessary, termination of the correspondent account.

(4) *Recordkeeping and reporting.* (i) A covered financial institution is required to document its compliance with the notice requirement set forth in this section.

(ii) Nothing in this section shall require a covered financial institution to report any information not otherwise required to be reported by law or regulation.

Kenneth A. Blanco,

Director, Financial Crimes Enforcement Network.

[FR Doc. 2019–23697 Filed 11–1–19; 8:45 am]

BILLING CODE 4810–02–P

[72] The estimated burden is two hours per financial institution—one hour for a senior executive of the financial institution to review and approve the notice to be provided to correspondent account holders, and one hour for a compliance officer to provide notice to correspondent account holders.

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Humanities

45 CFR Part 1169

RIN 3136–AA18

Implementation of the Privacy Act of 1974

AGENCY: National Endowment for the Humanities, National Foundation on the Arts and the Humanities.

ACTION: Final rule; technical correction.

SUMMARY: On July 19, 2019, the National Endowment for the Humanities (NEH) published in a final rule implementing its agency-specific Privacy Act regulation. This document makes technical corrections to that rule.

DATES: Effective November 4, 2019.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Deputy General Counsel, Office of the General Counsel, National Endowment for the Humanities, 400 Seventh Street SW, Room 4060, Washington, DC 20506; (202) 606–8322; *gencounsel@neh.gov.*

SUPPLEMENTARY INFORMATION: On July 19, 2019, NEH published a final rule at 84 FR 34788 implementing its agency-specific Privacy Act regulation. That rule amended 45 CFR chapter XI, subchapter D, by adding part 1169.

When NEH added that part, the paragraphs within § 1169.8 were incorrectly designated because there were two paragraphs (b). This action corrects this error by redesignating the second paragraph (b) through paragraph (g) as paragraphs (c) through (h).

List of Subjects in 45 CFR Part 1169

Administrative practice and procedure, Privacy.

For the reasons set forth in the preamble, the National Endowment for the Humanities amends 45 CFR part 1169 as follows:

PART 1169—PRIVACY ACT REGULATIONS

■ 1. The authority citation for part 1169 continues to read as follows:

Authority: 5 U.S.C. 552a(f).

§ 1169.8 [Amended]

■ 2. Amend § 1169.8 by redesignating the second paragraph (b) through paragraph (g) as paragraphs (c) through (h).

Dated: October 8, 2019.

Elizabeth Voyatzis,

Deputy General Counsel, National Endowment for the Humanities.

[FR Doc. 2019–22374 Filed 11–1–19; 8:45 am]

BILLING CODE 7536–01–P

Proposed Rules

Federal Register
Vol. 84, No. 213
Monday, November 4, 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.

DEPARTMENT OF ENERGY

10 CFR Part 810

RIN 1994–AA05

Assistance to Foreign Atomic Energy Activities

AGENCY: National Nuclear Security Administration (NNSA), Department of Energy (DOE).

ACTION: Extension of public comment period.

SUMMARY: The U.S. Department of Energy (''DOE'') is extending the public comment period for its proposed rule establishing procedures for the imposition of civil penalties for violations of certain provisions of the Atomic Energy Act of 1954 (AEA). The notice of proposed rulemaking (NOPR) provided for a public comment period ending November 4, 2019. On October 18, 2019 DOE received a comment requesting a 90-day comment period extension and a public meeting. DOE is extending the public comment period for submitting comments on the NOPR by 30 days to December 4, 2019.

DATES: The comment period for the proposed rulemaking published on October 3, 2019, 84 FR 52819, is extended. Comments, data, and information regarding this rulemaking must be submitted no later than December 4, 2019.

ADDRESSES: Interested persons may submit comments, identified by RIN 1994–AA05, by any of the following methods:

1. *Federal Rulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

2. *Email: Part810@nnsa.doe.gov*. Include RIN 1994–AA05 in the subject line of the message.

3. *Mail:* Katie Strangis, Office of Nonproliferation and Arms Control, NA–24, National Nuclear Security Administration, Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585. Due to potential delays in DOE's receipt and processing of mail sent through the U.S. Postal Service, DOE encourages responders to submit comments electronically to ensure timely receipt.

All submissions must include the RIN for this rulemaking, RIN 1994–AA05. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Comment Procedures'' heading of the **SUPPLEMENTARY INFORMATION** section of the NOPR at 84 FR 52822. For access to the docket to read background documents, or comments received, go to the Federal Rulemaking Portal at *https://www.regulations.gov/document?D=DOE_FRDOC_0001-3863*.

FOR FURTHER INFORMATION CONTACT: Ms. Katie Strangis, Senior Policy Advisor, Office of Nonproliferation and Arms Control (NPAC), National Nuclear Security Administration, Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585, telephone (202) 586–8623 or email *Katie.Strangis@nnsa.doe.gov*; Mr. Thomas Reilly, Office of the General Counsel, GC–53, Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585, telephone (202) 586–3417; or Mr. Zachary Stern, Office of the General Counsel, National Nuclear Security Administration, Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585, telephone (202) 586–8627.

SUPPLEMENTARY INFORMATION: On October 3, 2019, DOE published a NOPR in the **Federal Register** (84 FR 52819) to propose procedures for the imposition of civil penalties for violations of the provisions of the Atomic Energy Act of 1954 (AEA) that restrict participation by U.S. persons in the development or production of special nuclear material outside of the United States. The proposed procedures would be incorporated in the DOE regulations on Assistance to Foreign Atomic Energy Activities (10 CFR part 810). Comments on the proposed procedures were due by November 4, 2019. On October 18, 2019, DOE received a comment from Nuclear Energy Institute (NEI) requesting a 90-day comment period extension. DOE has reviewed the NEI request and considered the benefit to the public in providing additional time for comments on the NOPR. DOE has also considered the fact that timely implementation of this rule is important for national security, since the proposed civil penalties procedures would serve to deter illicit transfers of controlled nuclear technology and assistance.

Accordingly, DOE has determined that an extension of the comment period is appropriate and is hereby extending the comment period by 30 days, until December 4, 2019. DOE has determined to not hold a public meeting because the resources necessary to do so are greater than the benefit that could be achieved. DOE assesses that a 30 day extension strikes an appropriate balance between the requestor's desire for additional time and the national security benefits of implementing this rulemaking on a timely basis.

Signed in Washington, DC, on October 25, 2019.

Sean Oehlbert,

Director, Office of Nonproliferation Policy.

[FR Doc. 2019–23922 Filed 11–1–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0860; Product Identifier 2019–NM–123–AD]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2019–03–14, which applies to certain Dassault Aviation Model FAN JET FALCON, FAN JET FALCON SERIES C, D, E, F, and G airplanes. AD 2019–03–14 requires revising the existing maintenance or inspection program, as applicable, to incorporate new maintenance requirements and airworthiness limitations. Since AD 2019–03–14 was issued, the FAA has determined that new or more restrictive airworthiness limitations are necessary. This proposed AD would require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA is

proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by December 19, 2019.

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

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

For service information identified in this NPRM, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; internet *https://www.dassaultfalcon.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

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–2019–0860; 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 NPRM, the regulatory 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 FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2019–0860; Product Identifier 2019–NM–123–AD'' at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. The FAA will consider all comments received by the closing date and may amend this proposed AD based on those comments.

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

Discussion

The FAA issued AD 2019–03–14, Amendment 39–19566 (84 FR 7269, March 4, 2019) (''AD 2019–03–14''), for certain Dassault Aviation Model FAN JET FALCON, FAN JET FALCON SERIES C, D, E, F, and G airplanes. AD 2019–03–14 requires revising the existing maintenance or inspection program, as applicable, to incorporate new maintenance requirements and airworthiness limitations. AD 2019–03–14 resulted from a determination that new or more restrictive airworthiness limitations are necessary. The FAA issued AD 2019–03–14 to address, among other things, fatigue cracking and damage in principal structural elements; such fatigue cracking and damage could result in reduced structural integrity of the airplane.

Actions Since AD 2019–03–14 Was Issued

Since AD 2019–03–14 was issued, the FAA has determined that new or more restrictive airworthiness limitations are necessary.

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019–0142, dated June 17, 2019 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Dassault Aviation Model FAN JET FALCON, FAN JET FALCON SERIES C, D, E, F, and G airplanes.

This proposed AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address continued structural integrity of the airplane. See the MCAI for additional background information.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0860.

Related Service Information Under 1 CFR Part 51

Dassault Aviation has issued Chapter 5–40–01, Airworthiness Limitations, Revision 10, dated January 1, 2019, of the Dassault Aviation Falcon 20 Maintenance Manual, specifically for aircraft that have incorporated the supplemental structural inspection program (SSIP). This service information describes airworthiness limitations for safe life limits.

This proposed AD would also require Chapter 5–40–01, Airworthiness Limitations, DMD 44729, Revision 9, dated November 29, 2017, of the Dassault Aviation Falcon 20 Maintenance Manual, which the Director of the Federal Register approved for incorporation by reference as of April 8, 2019 (84 FR 7269, March 4, 2019).

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

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

Proposed Requirements of This NPRM

This proposed AD would retain all requirements of AD 2019–03–14. This proposed AD would also require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations.

This proposed AD would require revisions to certain operator maintenance documents to include new actions (*e.g.,* inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance according to paragraph (l)(1) of this proposed AD.

Costs of Compliance

The FAA estimates that this proposed AD affects 61 airplanes of U.S. registry.

The FAA estimates the following costs to comply with this proposed AD:

The FAA estimates the total cost per operator for the retained actions from AD 2019–03–14 to be $7,650 (90 work-hours × $85 per work-hour).

The FAA has determined that revising the maintenance or inspection program takes an average of 90 work-hours per operator, although the FAA recognizes that this number may vary from operator to operator. In the past, the FAA has estimated that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate.

The FAA estimates the total cost per operator for the new proposed actions to be $7,650 (90 work-hours × $85 per work-hour).

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.

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2019–03–14, Amendment 39–19566 (84 FR 7269, March 4, 2019); and adding the following new AD:

Dassault Aviation: Docket No. FAA–2019–0860; Product Identifier 2019–NM–123–AD.

(a) Comments Due Date

The FAA must receive comments by December 19, 2019.

(b) Affected ADs

(1) This AD replaces AD 2019–03–14, Amendment 39–19566 (84 FR 7269, March 4, 2019) (''AD 2019–03–14'').

(2) This AD affects AD 2010–26–05, Amendment 39–16544 (75 FR 79952, December 21, 2010) (''AD 2010–26–05'').

(c) Applicability

This AD applies to Dassault Aviation Model FAN JET FALCON, FAN JET FALCON SERIES C, D, E, F, and G airplanes, certificated in any category, on which the supplemental structural inspection program (SSIP) has been incorporated into the airplane's maintenance program.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time limits/maintenance checks.

(e) Reason

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address, among other things, fatigue cracking and damage in principal structural elements; such fatigue cracking and damage could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Retained Revision, With No Changes

This paragraph restates the requirements of paragraph (g) of AD 2019–03–14, with no changes. Within 90 days after April 8, 2019 (the effective date of AD 2019–03–14), revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in Chapter 5–40–01, Airworthiness Limitations, DMD 44729, Revision 9, dated November 29, 2017, of the Dassault Aviation Falcon 20 Maintenance Manual. The initial compliance time for doing the tasks is at the time specified in Chapter 5–40–01, Airworthiness Limitations, DMD 44729, Revision 9, dated November 29, 2017, of the Dassault Aviation Falcon 20 Maintenance Manual, or within 90 days after April 8, 2019 (the effective date of AD 2019–03–14), whichever occurs later. Where the threshold column in the table in paragraph B, Mandatory Maintenance Operations, of Chapter 5–40–01, Airworthiness Limitations, DMD 44729, Revision 9, dated November 29, 2017, of the Dassault Aviation Falcon 20 Maintenance Manual specifies a compliance time in years, those compliance times start from the date of issuance of the original airworthiness certificate or date of issuance of the original export certificate of airworthiness.

(h) Retained No Alternative Actions or Intervals With a New Exception

This paragraph restates the requirements of paragraph (h) of AD 2019–03–14, with a new exception. Except as required by paragraph (i) of this AD, after accomplishing the revision required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions and intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (l)(1) of this AD.

(i) New Requirement of This AD: Maintenance or Inspection Program Revision

Within 90 days after the effective date of this AD, revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in Chapter 5–40–01, Airworthiness Limitations, Revision 10, dated January 1, 2019, of the Dassault Aviation Falcon 20 Maintenance Manual. The initial compliance time for doing the tasks is at the time specified in Chapter 5–40–01, Airworthiness Limitations, Revision 10, dated January 1, 2019, of the Dassault Aviation Falcon 20 Maintenance Manual, or within 90 days after the effective

date of this AD, whichever occurs later. Where the threshold column in the table in paragraph B, Mandatory Maintenance Operations, of Chapter 5–40–01, Airworthiness Limitations, Revision 10, dated January 1, 2019, of the Dassault Aviation Falcon 20 Maintenance Manual specifies a compliance time in years, those compliance times start from the date of issuance of the original airworthiness certificate or the original export certificate of airworthiness. Accomplishing the actions required by this paragraph terminates the actions required by paragraph (g) of this AD.

(j) New No Alternative Actions or Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (i) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions or intervals are approved as an AMOC in accordance with the procedures specified in paragraph (l)(1) of this AD.

(k) Terminating Actions for Certain Actions in AD 2010–26–05

Accomplishing the actions required by paragraph (g) or (i) of this AD terminates the requirements of paragraph (g)(1) of AD 2010–26–05, for Dassault Aviation Model FAN JET FALCON, FAN JET FALCON SERIES C, D, E, F, and G airplanes.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (m)(2) of this AD. Information may be emailed to *9-ANM-116-AMOC-REQUESTS@faa.gov.*

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

(ii) AMOCs approved previously for AD 2019–03–14 are approved as AMOCs for the corresponding provisions of this AD.

(2) *Contacting the Manufacturer:* As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Union Aviation Safety Agency (EASA); or Dassault Aviation's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2019–0142, dated June 17, 2019, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0860.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226.

(3) For service information identified in this AD, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; internet *https://www.dassaultfalcon.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on October 29, 2019.

Dionne Palermo,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–23990 Filed 11–1–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–123112–19]

RIN 1545–BP51

The Treatment of Certain Interests in Corporations as Stock or Indebtedness

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: This document announces that the Department of the Treasury (Treasury Department) and the IRS intend to issue proposed regulations regarding the treatment of certain interests in corporations as stock or indebtedness and requests comments from the public regarding the contemplated rules. This document also announces that, following the expiration of the 2016 Temporary Regulations (described in the Background section of this advance notice of proposed rulemaking), a taxpayer may rely on the 2016 Proposed Regulations (also described in the Background) until further notice is given in the **Federal Register**, provided that the taxpayer consistently applies the rules in the 2016 Proposed Regulations in their entirety.

DATES: Written or electronic comments must be received by February 3, 2020.

ADDRESSES: Submit electronic submissions via the Federal eRulemaking Portal at *https://www.regulations.gov* (indicate IRS and REG–123112–19) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The 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–123112–19), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning the proposals, Azeka J. Abramoff at (202) 317–6938; concerning submissions of comments, Regina Johnson at (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

I. Overview

Section 385 authorizes the Secretary of the Treasury or his delegate (Secretary) to prescribe rules to determine whether an interest in a corporation is treated as stock or indebtedness (or as in part stock and in part indebtedness). On October 21, 2016, the Treasury Department and the IRS published T.D. 9790 in the **Federal Register** (81 FR 72858), which included final regulations under section 385 and temporary regulations under section 385 (Temporary Regulations). On the same date, the Treasury Department and the IRS also published a notice of proposed rulemaking (REG–130314–16) in the **Federal Register** (81 FR 72751) (2016 Proposed Regulations) by cross-reference to the Temporary Regulations, which include §§ 1.385–3T and 1.385–4T. Technical corrections to the final regulations and the Temporary Regulations were published in the **Federal Register** (82 FR 8169) on January 24, 2017.

The final regulations under section 385, the Temporary Regulations, and the 2016 Proposed Regulations address the classification of certain related-party debt as debt or equity for Federal tax purposes. Treasury Decision 9790 included rules set forth in § 1.385–2, which establish minimum documentation requirements that ordinarily must be satisfied in order for debt obligations among related parties to be treated as debt for Federal tax purposes (Documentation Regulations). Treasury Decision 9790 also included §§ 1.385–3, 1.385–3T, and 1.385–4T, which treat as stock certain debt that is issued by a corporation to a controlling

shareholder in a distribution or in another related-party transaction that achieves an economically similar result (the Distribution Regulations). The Distribution Regulations are applicable for taxable years ending on or after January 19, 2017.

The Temporary Regulations set forth rules regarding the treatment under the Distribution Regulations of certain qualified short-term debt instruments, transactions involving controlled partnerships, and transactions involving consolidated groups. The Temporary Regulations apply to taxable years ending on or after January 19, 2017. The Temporary Regulations expired on October 13, 2019. See section 7805(e); § 1.385–3T(l); § 1.385–4T(h).

The 2016 Proposed Regulations cross-referencing the Temporary Regulations are proposed to apply to taxable years ending on or after January 19, 2017; in contrast to the Temporary Regulations, the 2016 Proposed Regulations do not expire.

II. Executive Order 13789

Executive Order 13789 (E.O. 13789), issued on April 21, 2017, instructed the Secretary to review all significant tax regulations issued on or after January 1, 2016, and to take concrete action to alleviate the burdens of regulations that (i) impose an undue financial burden on U.S. taxpayers; (ii) add undue complexity to the Federal tax laws; or (iii) exceed the statutory authority of the IRS. E.O. 13789 further instructed the Secretary to submit to the President within 60 days a report (First Report) that identifies regulations that meet these criteria. Notice 2017–38, 2017–30 I.R.B. 147, which was published on July 24, 2017, included the final section 385 regulations in a list of eight regulations identified by the Secretary in the First Report as meeting at least one of the first two criteria specified in E.O. 13789.

E.O. 13789 further instructed the Secretary to submit to the President a report (Second Report) that recommended specific actions to mitigate the burden imposed by regulations identified in the First Report. On October 16, 2017, the Secretary published in the **Federal Register** the Second Report (82 FR 48013), which stated that (i) the Treasury Department and the IRS were considering a proposal to revoke the Documentation Regulations as issued and (ii) the Treasury Department will reassess the distribution regulations in light of impending tax reform and the Treasury Department and the IRS may then propose more streamlined and targeted regulations. On September 24, 2018, the Treasury Department and the IRS issued proposed regulations that, if finalized, would remove the Documentation Regulations from the Code of Federal Regulations. See 83 FR 48265 (September 24, 2018). The Treasury Department and the IRS are publishing in the Rules section of this issue of the **Federal Register** final regulations that remove the Documentation Regulations.

Some taxpayers submitted comments in response to E.O. 13789 and the September 2018 proposed regulations recommending that the Treasury Department and the IRS revoke the Distribution Regulations in addition to the Documentation Regulations, while another comment recommended that the Treasury Department and the IRS issue more streamlined and targeted Distribution Regulations. This advance notice of proposed rulemaking announces that the Treasury Department and the IRS intend to propose more streamlined and targeted Distribution Regulations.

III. The Distribution Regulations

Under the Distribution Regulations' general rule, the issuance of a debt instrument by a member of an expanded group to another member of the same expanded group in a distribution, or an economically similar transaction, may result in the treatment of the debt instrument as stock. See § 1.385–3(b)(2). The Distribution Regulations include a funding rule that treats as stock a debt instrument that is issued as part of a series of transactions that achieves a result similar to a distribution of a debt instrument. See § 1.385–3(b)(3)(i). Specifically, § 1.385–3(b) treats as stock a debt instrument that was issued in exchange for property, including cash, to fund a distribution to an expanded group member or another transaction that achieves an economically similar result. Id. Furthermore, the Distribution Regulations include a per se rule, which treats a debt instrument as funding a distribution to an expanded group member or other transaction with a similar economic effect if it was issued in exchange for property during the period beginning 36 months before and ending 36 months after the issuer of the debt instrument made the distribution or undertook a transaction with a similar economic effect. See § 1.385–3(b)(3)(iii). The Distribution Regulations also include several exceptions limiting their scope. See, *e.g.,* § 1.385–3(c).

The Distribution Regulations address debt instruments that do not finance any new investment in the operations of the borrower and therefore have the potential to create significant Federal tax benefits, including interest deductions that erode the U.S. tax base, without having meaningful non-tax significance. The Treasury Department and the IRS are cognizant that a complete withdrawal of the Distribution Regulations could restore incentives for multinational corporations to generate additional interest deductions without new investment. Accordingly, the Treasury Department and the IRS have determined that the Distribution Regulations continue to be necessary at this time.

Explanation of Contemplated Regulations

Pursuant to E.O. 13789, the Treasury Department and the IRS intend to issue proposed regulations modifying the Distribution Regulations. To make the Distribution Regulations more streamlined and targeted, the Treasury Department and the IRS intend to issue proposed regulations substantially modifying the funding rule, including by withdrawing the per se rule. The Treasury Department and the IRS intend that the proposed regulations would not treat a debt instrument as funding a distribution or economically similar transaction solely because of their temporal proximity; rather, the proposed regulations would apply the funding rule to a debt instrument only if its issuance has a sufficient factual connection to a distribution to a member of the taxpayer's expanded group or an economically similar transaction (for example, when the funding transaction and distribution or economically similar transaction are pursuant to an integrated plan). Thus, under the proposed regulations, a debt instrument issued without such a connection to a distribution or similar transaction would not be treated as stock. As a result, the proposed distribution regulations would be more streamlined and targeted while continuing to deter tax-motivated uneconomic activity. As part of the intended revisions of the funding rule, the Treasury Department and the IRS also are considering substantial revisions to, or removal of, certain exceptions in the regulations, consistent with the revised standard. The proposed distribution regulations would not alter materially the definition of a covered member (defined in § 1.385–1(c)(2) as a member of an expanded group that is a domestic corporation).

Proposed Applicability Date

The Treasury Department and the IRS intend to provide that the proposed regulations would apply to taxable years beginning on or after the date of publication of the Treasury decision

adopting those rules as final regulations in the **Federal Register**.

Reliance on the 2016 Proposed Regulations

For periods after October 13, 2019 (the expiration date of the Temporary Regulations), a taxpayer may rely on the 2016 Proposed Regulations until further notice is given, provided that the taxpayer consistently applies the rules in the 2016 Proposed Regulations in their entirety.

Request for Comments

The Treasury Department and the IRS request comments on all aspects of the rules described in part III of this advance notice of proposed rulemaking. In particular, the Treasury Department and the IRS request comments on the appropriate standard for determining the existence of a connection between a debt instrument and a distribution or economically similar transaction under the funding rule. For example, the funding rule could apply solely in cases in which a debt instrument is issued as part of an overall plan to fund the distribution or economically similar transaction. The Treasury Department and the IRS also request comments on whether the proposed regulations should include particular factors that indicate when the funding rule applies and factors that indicate when the funding rule does not apply. The Treasury Department and the IRS also request comments on what additional guidance, if any, should be issued (or which provisions should be eliminated from the final regulations) to reduce the compliance burdens associated with the Distribution Regulations. The Treasury Department and the IRS also request comments on how the Distribution Regulations may affect small businesses. All comments will be available at *http://www.regulations.gov* or upon request.

Effect on Other Documents

Notice 2019–58, 2019–44 I.R.B. 1022 (October 28, 2019), which addresses the status of the 2016 Proposed Regulations after October 13, 2019, is obsoleted.

Statement of Availability

IRS Notices and other guidance cited in this document are published in the Internal Revenue Bulletin and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *https://www.irs.gov*.

Drafting Information

The principal author of this advance notice of proposed rulemaking is Azeka J. Abramoff of the Office of Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in its development.

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2019–23819 Filed 10–31–19; 4:15 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

31 CFR Part 150

RIN 1505–AC59

Assessment of Fees on Certain Bank Holding Companies and Nonbank Financial Companies Supervised by the Federal Reserve Board To Cover the Expenses of the Financial Research Fund

AGENCY: Departmental Offices, Treasury.

ACTION: Proposed rule.

SUMMARY: The Department of the Treasury (''Treasury'') is requesting comment on a proposed rule to implement section 401 of the Economic Growth, Regulatory Relief, and Consumer Protection Act (the ''Economic Growth Act''), which amends section 155 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the ''Dodd-Frank Act''). As amended, section 155 requires the Secretary of the Treasury to establish, by regulation, an assessment schedule applicable to bank holding companies with total consolidated assets of $250 billion or greater and nonbank financial companies supervised by the Board of Governors of the Federal Reserve System (''the Board''), to collect assessments equal to the total expenses of the Office of Financial Research (the ''OFR''). The Department is also proposing other amendments to the part to simplify the method for determining the amount of total assessable assets for foreign banking organizations, which have been made possible by the introduction of a new regulatory data source.

DATES: Comments must be received by December 4, 2019.

ADDRESSES: Submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov,* or by mail to: U.S. Department of the Treasury, Office of Financial Research, Attn: John Zitko, 717 14th Street NW, Washington, DC 20220. Because mail in the Washington, DC area may be subject to delay, it is recommended that comments be submitted electronically. Please include your name, affiliation, address, email address, and telephone number in your comment. Comments will be available for public inspection on *www.regulations.gov.* In general, all comments received, including attachments and other supporting materials, are part of the public record and will be made available to the public. Do not submit any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

FOR FURTHER INFORMATION CONTACT: John Zitko, Senior Counsel, OFR, (202) 927–8372, *john.zitko@ofr.treasury.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 155(d) of the Dodd-Frank Act directs the Secretary of the Treasury to establish, by regulation, and with the approval of the Financial Stability Oversight Council (the ''Council''), an assessment schedule to collect assessments from certain companies equal to the total expenses of the OFR. Included in the OFR's expenses are expenses of the Council, pursuant to section 118 of the Dodd-Frank Act, and certain expenses of the Federal Deposit Insurance Corporation (the ''FDIC''), pursuant to section 210 of the Dodd-Frank Act. Section 401 of the Economic Growth Act, Public Law 115–174, also provides that any bank holding company, regardless of asset size, that has been identified as a global systemically important bank (''G–SIB'') under § 217.402 of title 12, Code of Federal Regulations, shall be considered a bank holding company with total consolidated assets equal to or greater than $250 billion for purposes of section 155(d) of the Dodd-Frank Act. On May 21, 2012, Treasury published a final regulation implementing section 155(d) in the **Federal Register**, codified at 31 CFR part 150 (the ''Original Rules''). Before the enactment of the Economic Growth Act, pursuant to section 155(d) and the implementing regulation, Treasury collected assessments from bank holding companies with total consolidated assets of $50,000,000,000 or greater and nonbank financial companies supervised by the Board.

On May 24, 2018, the Economic Growth Act was signed into law. Section 401(c)(1) of the Economic Growth Act replaced the $50 billion reference in section 155(d) of the Dodd-Frank Act with $250 billion. In addition, section 401(f) of the Economic Growth Act required any bank holding company identified as a G–SIB pursuant

to 12 CFR 217.402 to be considered a bank holding company with total consolidated assets equal to or greater than $250 billion for purposes of section 155(d) of the Dodd-Frank Act. As a result of this statutory amendment, bank holding companies with less than $250 billion in total consolidated assets that are not G–SIBs are not to be assessed under Dodd-Frank Act section 155(d).

The Economic Growth Act sets forth two different effective dates. For bank holding companies with total consolidated assets of less than $100 billion, it became effective on May 24, 2018 (the date of enactment). For bank holding companies with total consolidated assets of $100 billion or more and for G–SIBs, the effective date is November 24, 2019 (18 months after the date of enactment). This proposed rule is, in part, intended to implement section 401.

Under section 118 of the Dodd-Frank Act, the expenses of the Council are treated as expenses of, and are paid by, the OFR. In addition, under section 210 of the Dodd-Frank Act, certain implementation expenses of the FDIC associated with the FDIC's orderly liquidation authority are treated as expenses of the Council,[1] and the FDIC is directed to periodically submit requests for reimbursement to the Chairperson of the Council. The total expenses for the OFR therefore include the combined expenses of the OFR and the Council and certain expenses of the FDIC. All of these expenses are paid out of the Financial Research Fund (the ''FRF''), a fund managed by Treasury.

The Council was established by the Dodd-Frank Act to identify risks to U.S. financial stability, promote market discipline, and respond to emerging threats to the stability of the U.S. financial system. The Council is chaired by the Secretary of the Treasury, and its 15 members include all of the federal financial regulators, an independent member with insurance expertise appointed by the President, and state financial regulators.

The OFR was established within Treasury by the Dodd-Frank Act to support the Council and its member agencies. Among the OFR's key duties are:

- Collecting data on behalf of the Council and proving such data to the Council and member agencies;
- Standardizing the types and formats of data reported and collected;
- Performing research;
- Developing tools for risk measurement and monitoring; and
- Reporting to Congress and the public on the OFR's assessment of significant financial market developments and potential emerging threats to U.S. financial stability.

II. This Proposed Rule

Under this proposed rule, Treasury would implement the changes to the FRF assessments required by the Economic Growth Act. The proposed rule would also make certain other amendments to 31 CFR part 150 to simplify the method for determining the amount of total assessable assets for certain entities and would remove outdated references to the initial assessment period, which concluded in 2013, and other non-substantive changes to add clarifying or remove redundant language.

Treasury is seeking comments on all aspects of this proposed rulemaking.

a. Determination of Assessed Companies

To impose assessments under section 155 of the Dodd-Frank Act, Treasury must identify companies that are subject to the assessment. As described in the Original Rules, and below, Treasury works closely with the Board to determine the population of assessed companies.

The original text of Dodd-Frank Act section 155(d) required assessments to be collected from bank holding companies with total consolidated assets of $50 billion or greater and nonbank financial companies supervised by the Board. The Economic Growth Act raised the asset threshold for bank holding companies to $250 billion and also stated that a bank holding company, regardless of asset size, that has been identified as a G–SIB under § 217.402 of title 12, Code of Federal Regulations, shall be considered a bank holding company with total consolidated assets equal to or greater than $250 billion for purposes of section 155(d) of the Dodd-Frank Act.

Accordingly, we are proposing changes to the definitions of ''Assessed Company'' and ''Total Assessable Assets'' in 12 CFR 150.2, as well as the deletion of a reference to foreign banking organizations with less than $50 billion in 12 CFR 150.5, in accordance with the clear mandate of the Economic Growth Act with respect to an increase in the asset threshold from $50 billion to $250 billion and the inclusion of G–SIBs within the scope of companies subject to assessments under section 155.

b. Determination of Total Assessable Assets

i. Foreign Banking Organizations

At the time of adoption of the Original Rules, there was no single regulatory reporting form that provided a foreign banking organization's total assets of combined U.S. operations, including its U.S. branches, agencies, and subsidiaries. The preamble to the Original Rules specifically noted the possibility that reporting requirements for foreign banking organizations would change over time and that the list of reports would need to be adjusted.[2] To allow for the possibility of these changes, the Original Rules did not include a list of specific reference reports for foreign banking organizations, in contrast to U.S. bank holding companies. It was noted that calculating banking organizations' total assets of combined U.S. operations based on multiple reports could result in double-counting.[3] The preamble to the Original Rules stated that Treasury would make every effort to avoid double-counting, consulting with the Board and the affected firms as necessary, and that any questions could be addressed through the appeals process.[4]

After the adoption of the Original Rules, the Board modified its form FR Y–7Q by adding a line item for reporting the total combined assets of a foreign banking organization's U.S. operations. Line item 6 of part 1A of FR Y–7Q now requires reporting of the total combined assets of a top-tier foreign banking organization's U.S.-domiciled affiliates, branches, and agencies, excluding intercompany balances and intercompany transactions between those entities to the extent such items are not already eliminated in consolidation.[5] Accordingly, to simplify the method for determining the amount of total assessable assets for foreign banking organizations and to adopt an approach for foreign banking organizations that is comparable to the approach under the Original Rules for U.S. bank holding companies, we are proposing changes to the definition of

[1] Under Section 210(n)(10)(C) of the Dodd-Frank Act the term implementation expenses ''(i) means costs incurred by [the FDIC] beginning on the date of enactment of this Act, as part of its efforts to implement [Title II] that do not relate to a particular covered financial company; and (ii) includes the costs incurred in connection with the development of policies, procedures, rules, and regulations and other planning activities of the [FDIC] consistent with carrying out [Title II].''

[2] 77 FR 29890 (May 21, 2012).

[3] 77 FR 29888–89 (May 21, 2012).

[4] 77 FR 29889 (May 21, 2012).

[5] See Federal Reserve, The Capital and Asset Report for Foreign Banking Organizations—FR Y–7Q, available at *https://www.federalreserve.gov/reportforms/forms/FR_Y-7Q20190331_f.pdf.*

''total assessable assets'' by specifying that the calculation of a foreign banking organization's total assessable assets shall be based on the data reported in the FR Y–7Q.

ii. Timing of Determination Dates, Billing, and Collection

Under the Original Rules, assessments are semiannual. On the specified determination date before each assessment period, Treasury determines the pool of assessed companies, which receive confirmation statements. After any appeals, assessments are debited from assessed companies' accounts on the assessment payment date.

The Original Rules generally use a period of four calendar quarters to measure the total assessable assets of both U.S. and foreign entities for assessments. Thus, for the assessment period with a November 30 determination date, total assessable assets are based on the company's regulatory filings for the fourth quarter of the previous calendar year and the first three quarters of the same calendar year. For the assessment period with a May 31 determination date, total assessable assets are based on the company's filings for the last three quarters of the previous year and the first quarter of the same calendar year.

Both the Federal Reserve's form FR Y–9C, which the Original Rules require to be used to determine total assessable assets of U.S. bank holding companies, and the FR Y–7Q, which we are now proposing to use to determine the total assessable assets of foreign banking organizations, are quarterly reports. Their filing deadlines, however, are asynchronous, as the FR Y–9C generally must be filed within 40 calendar days after each calendar quarter,[6] and the FR Y–7Q generally must be filed within 90 calendar days after the quarter ends. The timing of updated reports therefore varies. For example, on the determination date of May 31 under the Original Rules, the FR Y–9C reports are already available for Q1 of the same year, but Q1 reports on FR Y–7Q are not due until approximately one month later (June 29).

To enable consistency in the timing of determining assessable assets for U.S. and foreign entities we are proposing to move each of the two semiannual determination dates one month earlier. Accordingly, the first determination date in each calendar year would be April 30 instead of the current May 31, and the second determination date would be October 31, instead of November 30. This proposed change would enable each assessment to be based on companies' filings for the last two calendar quarters of the previous year and the first two quarters of the current calendar year for assessment periods with an October 31 determination date, and all four quarters of the previous calendar year for assessment periods with an April 30 determination date.

Consistent with Treasury's existing process, before each assessment period, after determining the pool of assessed companies and publishing an assessment fee rate, Treasury will calculate the assessment fee for each assessed company, send an electronic billing notification to each assessed company, and, on the assessment payment date, initiate a direct debit to each company's account through *www.pay.gov* to collect the assessments. Treasury proposes to retain the existing process, with one additional month added to the beginning of each cycle, as described above, while keeping the existing dates for the notice of fees, billing, and payment. In order to provide additional clarity as to when redetermination requests must be received from companies wishing to appeal their status as an assessed company or the total assessable assets that the Department has determined will be used for calculating the company's assessment, Treasury proposes to amend the reference to such date in 12 CFR 150.6(b) from ''one month'' to ''30 calendar days.''

The table below shows approximate dates of the proposed assessment billing and collection process:

Assessment period	Determination date	Confirmation statement date	Redetermination request deadline	Initial response to redetermination request	Publication of notice of fees*	Billing date	Payment date
1st semiannual assessment period (April–September).	October 31 ...	November 15 (or next business day).	30 calendar days from date of Confirmation Statement.	21 calendar days from receipt of Redetermination Request.	February 15 (or next business day).	March 1 (or prior business day).	March 15 (or next business day).
2nd semiannual assessment period (October–March).	April 30	May 15 (or next business day).	30 calendar days from date of Confirmation Statement.	21 calendar days from receipt of Redetermination Request.	August 15 (or next business day).	September 1 (or prior business day).	September 15 (or next business day).

*Rate published in the Notice of Fees.

The timeframe for sending confirmation statements and receiving appeals would remain the same. Specifically, confirmation statements would continue to be mailed no later than 15 calendar days after the determination date, and appeals by assessable companies would continue to be due one month later. In addition to promoting consistent measurements of U.S. and foreign entities, as noted above, adding a month to the beginning of the FRF assessments cycle would also afford assessed companies additional time to address appeals and make payment arrangements, and would provide Treasury additional time to calculate assessments and administer the billing process.

III. Administrative Law Matters

a. Regulatory Flexibility Act

Congress enacted the Regulatory Flexibility Act (the ''RFA'') to address concerns related to the effects of agency rules on small entities.[7] Treasury is sensitive to the impact its rules may impose on small entities. The RFA requires agencies either to provide an initial regulatory flexibility analysis with a proposed rule for which general notice of proposed rulemaking is required, or to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.[8]

Under regulations issued by the Small Business Administration, a ''small entity'' includes those firms within the ''Finance and Insurance'' sector with asset sizes that vary from $7.5 million in assets to $550 million or less in assets.[9] For purposes of the RFA, entities that are banks are considered small entities if their assets are less than or equal to $550 million.

[6] Reports as of December 31 are due 45 calendar days later.

[7] 5 U.S.C. 601 *et seq.*

[8] 5 U.S.C. 603(a).

[9] 13 CFR 121.201.

As discussed above, under section 155 of the Dodd-Frank Act, as amended by the Economic Growth Act, only bank holding companies with more than $250 billion in total consolidated assets, G–SIBs, and nonbank financial companies supervised by the Board will be subject to assessments under this proposed rule. As such, this proposed rule will not apply to small entities and a regulatory flexibility analysis is not required.

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 605(b), it is hereby certified that this proposed rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.

b. Paperwork Reduction Act

We estimate that there are certain direct costs associated with complying with these rules. On a one-time basis, assessed entities would be required to set up a bank account for fund transfers and provide the required information to Treasury through an information collection form. The form includes bank account routing information and contact information for the individuals at the company that will be responsible for setting up the account and ensuring that funds are available on the billing date. We estimate that approximately 20 companies could be affected, and that completing the form and submitting it to Treasury would take approximately 15 minutes. The aggregate paperwork burden is estimated at 5.0 hours. However, all of these companies have already established an account for payments or collections to the U.S. government pursuant to the Original Rules.

On a semiannual basis, assessed companies have the opportunity to review the confirmation statement and assessment bill. The Original Rules do not require the companies to conduct this review, but do permit it. We anticipate that at least some of the companies will conduct reviews, in part because the cost associated with it is very low.

The collection of information contained in this proposed rule has been submitted to the Office of Management and Budget (OMB) for review under the requirements of the Paperwork Reduction Act, 44 U.S.C. 3507(d).

Organizations and individuals desiring to submit comments concerning the collection of information in the proposed rule should direct them to: U.S. Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, or by email to *oira_submission@omb.eop.gov.* A copy of the comments should also be sent to Treasury at the addresses previously specified. Comments on the collection of information should be received by January 3, 2020.

Treasury specifically invites comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the mission of Treasury, and whether the information will have practical utility; (b) the accuracy of the estimate of the burden of the collections of information (see below); (c) ways to enhance the quality, utility, and clarity of the information collection; (d) ways to minimize the burden of the information collection, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to maintain the information.

The information collections are included in § 150.6.

c. Regulatory Planning and Review (Executive Orders 12866 and 13563)

This rule is not a significant regulatory action as defined in section 3(f) of Executive Order 12866 as supplemented by Executive Order 12563.

List of Subjects in 31 CFR Part 150

Bank holding companies, Financial Research Fund, Nonbank financial companies.

■ For the reasons set forth in the preamble, Treasury proposes to revise title 31, part 150, of the Code of Federal Regulations to read as follows:

PART 150—FINANCIAL RESEARCH FUND

Sec.

150.1 Scope.
150.2 Definitions.
150.3 Determination of assessed companies.
150.4 Calculation of assessment basis.
150.5 Calculation of assessments.
150.6 Notice and payment of assessments.

Authority: 12 U.S.C. 5345; 31 U.S.C. 321; 12 U.S.C. 5365 *note* (Section 401(d), Pub. L. 115–174, 132 Stat. 1358; Section 401(f), Pub. L. 115–174, 132 Stat. 1359).

§ 150.1 Scope.

The assessments contained in this part are made pursuant to the authority contained in 12 U.S.C. 5345.

§ 150.2 Definitions.

As used in this part:

Assessed company means:

(1) A bank holding company that has $250 billion or more in total assessable assets; or

(2) A bank holding company, regardless of asset size, that has been identified as a global systemically important bank holding company under § 217.402 of title 12, Code of Federal Regulations; or

(3) A nonbank financial company that the Council has determined under section 113 of the Dodd-Frank Act shall be supervised by the Board.

Assessment basis means, for a given assessment period, an estimate of the total expenses that are necessary or appropriate to carry out the responsibilities of the OFR and the Council as set out in the Dodd-Frank Act (including an amount necessary to reimburse reasonable implementation expenses of the Corporation that shall be treated as expenses of the Council pursuant to section 210(n)(10) of the Dodd-Frank Act).

Assessment fee rate, with regard to a particular assessment period, means the rate published by the Department for the calculation of assessment fees for that period.

Assessment payment date means:

(1) For any assessment period ending on March 31 of a given calendar year, September 15 of the prior calendar year; and

(2) For any assessment period ending on September 30 of a given calendar year, March 15 of the same year.

Assessment period means:

(1) Any period of time beginning on October 1 and ending on March 31 of the following calendar year; or

(2) Any period of time beginning on April 1 and ending on September 30 of the same calendar year.

Bank holding company means:

(1) A bank holding company as defined in section 2 of the Bank Holding Company Act of 1956 (12 U.S.C. 1841); or

(2) A foreign banking organization.

Board means the Board of Governors of the Federal Reserve System.

Corporation means the Federal Deposit Insurance Corporation.

Council means the Financial Stability Oversight Council.

Department means the Department of the Treasury.

Determination date means:

(1) For any assessment period ending on March 31 of a given calendar year, April 30 of the prior calendar year; and

(2) For any assessment period ending on September 30 of a given calendar year, October 31 of the prior calendar year.

Dodd-Frank Act means the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Foreign banking organization means a foreign bank or company that is treated

as a bank holding company for purposes of the Bank Holding Company Act of 1956, pursuant to section 8(a) of the International Banking Act of 1978 (12 U.S.C. 3106(a)).

OFR means the Office of Financial Research established by section 152 of the Dodd-Frank Act.

Total assessable assets means:

(1) For a bank holding company other than a foreign banking organization, the average of the company's total consolidated assets for the four quarters preceding the relevant determination date, as reported on the bank holding company's four most recent Consolidated Financial Statements for Bank Holding Companies—FR Y–9C filings;

(2) For any foreign banking organization, the average of the company's total assets of combined U.S. operations for the four quarters preceding the relevant determination date, as reported on the foreign banking organization's four most recent quarterly Capital and Asset Report for Foreign Banking Organizations—FR Y–7Q filings, or, if the foreign banking organization only files such form annually, the average of the two most recent annual filings on such form; or

(3) For a nonbank financial company that the Council has determined under section 113 of the Dodd-Frank Act shall be supervised by the Board, either the average of the company's total consolidated assets for the four quarters preceding the relevant determination date, if the company is a U.S. company, or the average of the total assets of the company's combined U.S. operations for the four quarters preceding the relevant determination date, if the company is a non-U.S. company.

§ 150.3 Determination of assessed companies.

(a) The determination that a bank holding company or a nonbank financial company is an assessed company will be made by the Department.

(b) The Department will apply the following principles in determining whether a company is an assessed company:

(1) For tiered bank holding companies for which a holding company owns or controls, or is owned or controlled by, other holding companies, the assessed company shall be the top-tier, regulated holding company.

(2) In situations where more than one top-tier, regulated bank holding company has a legal authority for control of a U.S. bank, each of the top-tier regulated holding companies shall be designated as an assessed company.

(3) In situations where a company has not filed four consecutive quarters of the financial reports referenced above for the most recent quarters (or two consecutive years for annual filers of the FR Y–7Q or successor form), such as may be true for companies that recently converted to a bank holding company, the Department will use, at its discretion, other financial or annual reports filed by the company, such as Securities and Exchange Commission (SEC) filings, to determine a company's total consolidated assets.

(4) In situations where a company does not report total consolidated assets in its public reports or where a company uses a financial reporting methodology other than U.S. generally accepted accounting principles (GAAP) to report on its U.S. operations, the Department will use, at its discretion, any comparable financial information that the Department may require from the company for this determination.

(c) Any company that the Department determines is an assessed company on a given determination date will be an assessed company for the entire assessment period related to such determination date, and will be subject to the full assessment fee for that assessment period, regardless of any changes in the company's assets or other attributes that occur after the determination date.

§ 150.4 Calculation of assessment basis.

For each assessment period, the Department will calculate an assessment basis that shall be sufficient to replenish the Financial Research Fund to a level equivalent to the sum of:

(a) Budgeted operating expenses for the OFR for the applicable assessment period;

(b) Budgeted operating expenses for the Council for the applicable assessment period;

(c) Budgeted capital expenses for the OFR for the 12-month period beginning on the first day of the applicable assessment period;

(d) Budgeted capital expenses for the Council for the 12-month period beginning on the first day of the applicable assessment period; and

(e) An amount necessary to reimburse reasonable implementation expenses of the Federal Deposit Insurance Corporation as provided under section 210(n)(10) of the Dodd-Frank Act.

§ 150.5 Calculation of assessments.

(a) For each assessed company, the Department will calculate the total assessable assets in accordance with the definition in § 150.2.

(b) The Department will allocate the assessment basis to the assessed companies in the following manner:

(1) Based on the sum of all assessed companies' total assessable assets, the Department will calculate the assessment fee rate necessary to collect the assessment basis for the applicable assessment period.

(2) The assessment payable by an assessed company for each assessment period shall be equal to the assessment fee rate for that assessment period multiplied by the total assessable assets of such assessed company.

§ 150.6 Notice and payment of assessments.

(a) No later than fifteen calendar days after the determination date, the Department will send to each assessed company a statement that:

(1) Confirms that such company has been determined by the Department to be an assessed company; and

(2) States the total assessable assets that the Department has determined will be used for calculating the company's assessment.

(b) If a company that is required to make an assessment payment for a given assessment period believes that the statement referred to in paragraph (a) of this section contains an error, the company may provide the Department with a written request for a revised statement. Such request must be received by the Department via email within 30 calendar days and must include all facts that the company requests the Department to consider. The Department will respond to all such requests within 21 calendar days of receipt thereof.

(c) No later than the 14 calendar days prior to the payment date for a given assessment period, the Department will send an electronic billing notification to each assessed company, containing the final assessment that is required to be paid by such assessed company.

(d) For the purpose of making the payments described in § 150.5, each assessed company shall designate a deposit account for direct debit by the Department through *www.pay.gov* or successor website. No later than the later of 30 days prior to the payment date for an assessment period, or [EFFECTIVE DATE OF THE FINAL RULE], each such company shall provide notice to the Department of the account designated, including all information and authorizations required by the Department for direct debit of the account. After the initial notice of the designated account, no further notice is required unless the company designates a different account for assessment debit

by the Department, in which case the requirements of the preceding sentence apply.

(e) Each assessed company shall take all actions necessary to allow the Department to debit assessments from such company's designated deposit account. Each such company shall, prior to each assessment payment date, ensure that funds in an amount at least equal to the amount on the relevant electronic billing notification are available in the designated deposit account for debit by the Department. Failure to take any such action or to provide such funding of the account shall be deemed to constitute nonpayment of the assessment. The Department will cause the amount stated in the applicable electronic billing notification to be directly debited on the appropriate payment date from the deposit account so designated.

(f) In the event that, for a given assessment period, an assessed company materially misstates or misrepresents any information that is used by the Department in calculating that company's total assessable assets, the Department may at any time re-calculate the assessment payable by that company for that assessment period, and the assessed company shall take all actions necessary to allow the Department to immediately debit any additional payable amounts from such assessed company's designated deposit account.

(g) If a due date under this section falls on a date that is not a business day, the applicable date shall be the next business day.

Dated: October 28, 2019.

Kipp Kranbuhl,

Principal Deputy Assistant Secretary, Financial Markets, Department of the Treasury.

[FR Doc. 2019–23906 Filed 11–1–19; 8:45 am]

BILLING CODE 4810–25–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2019–0043; FRL–10001–20–Region 6]

Air Plan Approval; Texas; Revisions To Control of Air Pollution by Permits for New Construction or Modification

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Pursuant to the Federal Clean Air Act (CAA or the Act), the United States Environmental Protection Agency (U.S. EPA) is proposing to approve revisions to the Texas (TX) State Implementation Plan (SIP) submitted on February 22, 2019 that revise the State's New Source Review (NSR) permitting rules contained in Title 30 of the Texas Administrative Code (TAC) Chapter 116. The EPA is also addressing portions of an April 16, 2014, SIP submittal pertaining to provisions regarding Greenhouse Gas (GHG) emissions that were invalidated by the United States Supreme Court. The February 22, 2019, SIP submittal appropriately revises the April 16, 2014, SIP provisions that were impacted by the Court's ruling.

DATES: Written comments must be received on or before December 4, 2019.

ADDRESSES: Submit your comments, identified by Docket No. 2017–1641–RUL, at *https://www.regulations.gov* or via email to *layton.elizabeth@epa.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact Elizabeth Layton, 214–665–2136, *layton.elizabeth@epa.gov.* For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

Docket: The index to the docket for this action is available electronically at *www.regulations.gov* and in hard copy at the U.S. EPA Region 6, 1201 Elm Street, Suite 500, Dallas, Texas 75270. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available at either location (*e.g.,* CBI).

FOR FURTHER INFORMATION CONTACT: Elizabeth Layton, Air Permits Section (ARPE), U.S. EPA Region 6, 1201 Elm Street, Suite 500, Dallas, TX 75270, 214–665–2136, *layton.elizabeth@epa.gov.* To inspect the hard copy materials, please schedule an appointment with Ms. Elizabeth Layton or Mr. Bill Deese at 214–665–7253.

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, we mean the United States Environmental Protection Agency.

I. Background

Section 110(a)(2)(C) of the CAA requires states to develop and submit to the EPA for approval into the SIP, preconstruction review and permitting programs applicable to certain new and modified stationary sources of air pollutants for attainment and nonattainment areas that cover both major and minor new sources and modifications, collectively referred to as the New Source Review (NSR) SIP. The CAA NSR SIP program is composed of three separate programs: Prevention of Significant Deterioration (PSD), Nonattainment New Source Review (NNSR), and Minor NSR. The EPA codified minimum requirements for these State permitting programs including public participation and notification requirements at 40 CFR 51.160–51.164. Requirements specific to construction of new stationary sources and major modifications in nonattainment areas are codified in 40 CFR 51.165 for the NNSR program. Requirements for permitting of new stationary sources and major modifications in attainment areas subject to PSD, including additional public participation requirements, are found at 40 CFR 51.166. This action addresses revisions to the Texas SIP submitted on February 22, 2019 by the Texas Commission on Environmental Quality (TCEQ) that amend the State's NSR permitting rules by amending the criteria for air pollution control permits for new construction or modification, as well as make other non-substantive revisions.

Additionally, this action addresses portions of an April 16, 2014, Texas SIP submittal that relate to the permitting of Greenhouse Gas Emissions (GHGs) for Step 2 or ''non-anyway'' sources.[1] The April 2014 submittal was affected by a United States Supreme Court ruling titled *Utility Air Regulatory Group (UARG)* v. *EPA* (134 S.Ct. 2427 (2014)) where the Court invalidated those portions of the federal rules that related

[1] For more detailed information please see our **Federal Register** action at 79 FR 66626 (November 10, 2014). Step 2 or ''non-anyway'' sources are sources that that would have been considered ''major'' under EPA's permitting program for PSD only because of their greenhouse gas emissions.

to the permitting of non-anyway sources.[2] Consequently, the State and EPA determined the portions of the State's SIP submittal that addressed ''non-anyway'' sources were no longer appropriate for SIP action.[3] As explained in more detail below, the February 22, 2019 GHG related revisions appropriately address the April 16, 2014, GHG provisions that were affected by the Court's decision.

II. The EPA's Evaluation

A. Evaluation of the February 22, 2019 SIP Submittal Revisions to the State's New Source Review Rules

On February 22, 2019, the TCEQ submitted revisions to the Texas SIP (Rule Project No. 2018–003–116–AI) revising their rules that address applicable requirements for air pollution control permits for new construction or modification under 30 TAC Chapter 116, Sections 116.114, 116.160, 116.164(a), 116.196, 116.198, 116.310, 116.611, and 116.615. Revisions to 30 TAC Chapter 116 were partly in response to the passage of House Bill (HB) 4181, 85th Texas Legislature, 2017 that amended Texas Health and Safety Code (THSC), § 382.055 to provide TCEQ with the option to use an electronic method or system to notify new source review (NSR) air permit holders that an air permit is scheduled for review.

The February 22, 2019 revisions revise the Texas SIP at 30 TAC Sections 116.160(b)(2), 116.164(a), 116.164(a)(3)–(5), 116.196(a), 116.310, 116.611(a), 116.615(2), and 116.615(2)(A)–(D). The revisions to 30 TAC Sections 116.196(a), 116.310, and 116.611(a) provide the State the ability to implement existing rules and regulations pertaining to the control of air quality by air permits utilizing electronic methods for various air permitting processes. These include permit renewal notification for Plant-wide Applicability Limit (PAL) permits, notification to permit holders of approaching permit expiration, and the ability to apply for standard permit registration via electronic methods. The substantive revisions at 30 TAC Section 116.615(2)(A) clarify registration requirements when a new facility is added to an existing operation authorized under standard permitting. Additional substantive revisions at 30 TAC Section 116.615(2)(B)–(D) clarify notification and registration requirements for changes in the representation of emissions at facilities authorized by standard permits for air quality.

Other amendments to 30 TAC Chapter 116 include revisions that are minor or non-substantive in nature and do not change the intent or substance of the originally approved SIP requirements; these minor and administrative type revisions to 30 TAC Sections 116.114(c)(3)(A), 116.196(b)–(f), 116.198(a), and 116.198(b) update cross references, correct grammar, and renumber existing SIP approved provisions. The accompanying Technical Support Document (TSD) for this action includes a comprehensive analysis and discussion of the submitted revisions to the Texas SIP that includes both the substantive and minor, non-substantive revisions. The TSD is included in the docket for this proposed rulemaking.

The EPA has determined it is appropriate to propose approval of the above-cited February 22, 2019, revisions to the Texas SIP as these amendments to the Texas air permitting process clarify existing processes and promote efficiency by implementing electronic notifications and registrations. These revisions are consistent with federal permitting regulations; therefore, these revisions will not interfere with attainment, reasonable further progress, or any other applicable requirements of the Act.

B. Evaluation of the April 16, 2014 and February 22, 2019 Revisions to New Source Review Permitting for GHG Emissions

As stated earlier, the State's February 22, 2019, SIP submittal appropriately revises provisions in 30 TAC Section 116 to be consistent with the U.S. Supreme Court's 2014 *UARG* v. *EPA* decision. The TCEQ originally submitted revisions to the Texas SIP on April 16, 2014 (adopted March 16, 2014) to address the permitting for GHG emissions.[4] That submittal contained provisions that would have required a permit applicant to conduct PSD review based solely on GHG emissions, commonly referred to as non-anyway or Step 2 GHG permitting. Based on the outcome of the 2014 U.S. Supreme Court decision, provisions that related to the permitting of non-anyway sources in 30 TAC Sections 116.160(a) and 116.164(a)(3)–(5) were no longer appropriate for SIP action. See 79 FR 66626. The February 22, 2019 submittal appropriately removes these provisions consistent with the Court's decision. Therefore, EPA has determined it is appropriate to approve the February 22, 2019 submitted revisions to 30 TAC Sections 116.160(a) and 116.164(a)(3)–(5) that remove the provisions. The February 22, 2019, revisions ensure that the Texas NSR program is consistent with the EPA's policy, guidance, case law and regulations for permitting GHG emissions; therefore, these revisions will not interfere with attainment, reasonable further progress, or any other applicable requirements of the Act. The TSD that is included in the docket for this proposed rulemaking contains a detailed analysis and discussion of these revisions.

III. Proposed Action

We are proposing to approve revisions to the Texas SIP that revise the State's New Source Review permit rules. We are also proposing to approve revisions to the Texas NSR rules related to the permitting of greenhouse gas emissions as being consistent with federal requirements. As explained in this proposed action and the accompanying TSD, we have determined that the revisions submitted on February 22, 2019, were developed in accordance with the CAA and EPA's regulations, case law, policy, and guidance for NSR permitting. Therefore, under section 110 of the CAA, the EPA proposes approval of the following revisions adopted on October 31, 2018 and submitted February 22, 2019:

- Revisions to 30 TAC Section 116.114;
- Revisions to 30 TAC Section 116.160;
- Revisions to 30 TAC Section 116.164(a);
- Revisions to 30 TAC Section 116.196;
- Revisions to 30 TAC Section 116.198;
- Revisions to 30 TAC Section 116.310;
- Revisions to 30 TAC Section 116.611; and
- Revisions to 30 TAC Section 116.615.

IV. Incorporation by Reference

In this action, we are proposing to include in a final rule, regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, we are proposing to incorporate by reference revisions to the Texas regulations as described in the Proposed Action section above. We have made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and in hard copy at the EPA Region 6 office

[2] Id. For more detail, please see 81 FR 68110 (October 3, 2016).

[3] Id. See the State's October 1, 2014 letter to EPA that is included in the docket to this action.

[4] We approved much of this submittal on November 10, 2014 (70 FR 66626). Docket No. EPA–R06–OAR–2013–0808.

(please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act 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 proposes to approve 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 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).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the proposed rule does not have tribal implications and 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).

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: October 25, 2019.

David Gray,

Acting Regional Administrator, Region 6.

[FR Doc. 2019–23676 Filed 11–1–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2019–0522; FRL–10001–07–Region 5]

Air Plan Approval; Ohio; Revisions to NO_X SIP Call Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve under the Clean Air Act (CAA) a request from the Ohio Environmental Protection Agency (Ohio EPA) to revise the Ohio State Implementation Plan (SIP) to incorporate revisions to Ohio Administrative Code (OAC) Chapter 3745–14 regarding the Nitrogen Oxides (NO_X) SIP Call. This SIP revision would approve alternative monitoring requirements for certain covered sources.

DATES: Comments must be received on or before December 4, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2019–0522 at *http://www.regulations.gov,* or via email to *aburano.douglas@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, 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, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Eric Svingen, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–4489, *svingen.eric@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This supplementary information section is arranged as follows:

I. What is the background of this SIP submission?
II. What is EPA's analysis of this SIP submission?
III. What action is EPA taking?
IV. Incorporation by Reference
V. Statutory and Executive Order Reviews

I. What is the background of this SIP submission?

Under CAA section 110(a)(2)(D)(i)(I), called the good neighbor provision, states are required to address interstate transport of air pollution. Specifically, the good neighbor provision provides that each state's SIP must contain provisions prohibiting emissions from within that state from contributing significantly to nonattainment of the National Ambient Air Quality Standards (NAAQS), or interfering with maintenance of the NAAQS, in any other state.

On October 27, 1998, EPA published the NO_X SIP Call, which required eastern states, including Ohio, to submit SIPs that prohibit excessive emissions of ozone season NO_X by implementing statewide emissions budgets (63 FR 57356). The NO_X SIP Call addressed the

good neighbor provision for the 1979 ozone NAAQS and was designed to mitigate the impact of transported NO_X emissions, one of the precursors of ozone. EPA developed the NO_X Budget Trading Program, an allowance trading program that states could adopt to meet their obligations under the NO_X SIP Call. This trading program allowed certain sources to participate in a regional cap and trade program: Electric Generating Units (EGUs) with capacity greater than 25 megawatts; and large non-EGUs, such as boilers and turbines, with a rated heat input greater than 250 million British thermal units per hour (MMBtu/hr). The NO_X SIP Call also identified potential reductions from Portland cement kilns and stationary internal combustion engines.

In fulfillment of the requirements of the NO_X SIP Call, Ohio EPA promulgated OAC Chapter 3745–14 which, among other things, required EGUs and large non-EGUs in the state to participate in the NO_X Budget Trading Program. On August 5, 2003, EPA published an action approving this initial version of OAC Chapter 3745–14 into the Ohio SIP (68 FR 46089).

On May 12, 2005, EPA published the Clean Air Interstate Rule (CAIR), which required eastern states, including Ohio, to submit SIPs that prohibited emissions consistent with annual and ozone season NO_X budgets and annual sulfur dioxide (SO_2) budgets (70 FR 25152). CAIR addressed the good neighbor provision for the 1997 ozone NAAQS and 1997 fine particulate matter ($PM_{2.5}$) NAAQS and was designed to mitigate the impact of transported NO_X emissions, a precursor of ozone as well as $PM_{2.5}$, as well as transported SO_2 emissions, another precursor of $PM_{2.5}$. Like the NO_X SIP Call, CAIR also established several trading programs that states could use as mechanisms to comply with the budgets. When the CAIR trading program for ozone season NO_X was implemented beginning in 2009, EPA discontinued administration of the NO_X Budget Trading Program, but the requirements of the NO_X SIP Call continued to apply.

To meet the requirements of CAIR, Ohio EPA promulgated OAC Chapter 3745–109, which required EGUs to participate in the CAIR annual SO_2 and annual and ozone season NO_X trading programs. Participation by EGUs in the CAIR trading program for ozone season NO_X addressed the state's obligation under the NO_X SIP Call for those units. Ohio EPA also opted to incorporate large non-EGUs previously regulated under OAC Chapter 3745–14 into OAC Chapter 3745–109, to meet the obligations of the NO_X SIP Call with respect to those units through the CAIR trading program as well. On September 25, 2009, EPA published an action approving OAC Chapter 3745–109 into the Ohio SIP (74 FR 48857).

The United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) initially vacated CAIR in 2008, but ultimately remanded the rule to EPA without vacatur to preserve the environmental benefits provided by CAIR. *North Carolina* v. *EPA,* 531 F.3d 896, modified, 550 F.3d 1176 (D.C. Cir. 2008). The ruling allowed CAIR to remain in effect temporarily until a replacement rule consistent with the court's opinion was developed. While EPA worked on developing a replacement rule, the CAIR program continued as planned with the NO_X annual and ozone season programs beginning in 2009 and the SO_2 annual program beginning in 2010.

On August 8, 2011, acting on the D.C. Circuit's remand, EPA published the Cross-State Air Pollution Rule (CSAPR) to replace CAIR and to address the good neighbor provision for the 1997 ozone NAAQS, the 1997 $PM_{2.5}$ NAAQS, and the 2006 $PM_{2.5}$ NAAQS (76 FR 48208). Through Federal Implementation Plans (FIPs), CSAPR required EGUs in eastern states, including Ohio, to meet annual and ozone season NO_X budgets and annual SO_2 budgets implemented through new trading programs. CSAPR also contained provisions that would sunset CAIR-related obligations on a schedule coordinated with the implementation of the CSAPR compliance requirements. Participation by a state's EGUs in the CSAPR trading program for ozone season NO_X generally addressed the state's obligation under the NO_X SIP Call for EGUs. However, CSAPR did not initially contain provisions allowing states to incorporate large non-EGUs into that trading program to meet the requirements of the NO_X SIP Call for non-EGUs.

CSAPR was intended to become effective January 1, 2012; however, the timing of CSAPR's implementation was impacted by subsequent litigation in which the D.C. Circuit stayed implementation of the rule pending judicial review. After subsequent litigation,[1] the court granted EPA's motion to lift the stay [2] and, on December 3, 2014, EPA issued an interim final rule, setting the updated effective date of CSAPR as January 1, 2015 (79 FR 71663). In accordance with the interim final rule, EPA stopped administering the CAIR trading programs with respect to emissions occurring after December 31, 2014, and EPA began implementing CSAPR on January 1, 2015.[3]

On October 26, 2016, EPA published the CSAPR Update, which established a new ozone season NO_X trading program for EGUs in eastern states, including Ohio, to address the good neighbor provision for the 2008 ozone NAAQS (81 FR 74504). As under CSAPR, participation by a state's EGUs in the new CSAPR trading program for ozone season NO_X generally addressed the state's obligation under the NO_X SIP Call for EGUs. The CSAPR Update also expanded options available to states for meeting NO_X SIP Call requirements for large non-EGUs by allowing states to incorporate those units into the new trading program.

After evaluating the various options available following the CSAPR Update, Ohio EPA chose to meet the ongoing NO_X SIP Call requirements for existing and new large non-EGUs by modifying its existing regulations at OAC Chapter 3745–14 to make the portion of the budget assigned to large non-EGUs under that program enforceable without an allowance trading mechanism. Ohio also rescinded its CAIR trading program rules in OAC Chapter 3745–109 in full. On September 17, 2019, EPA published an action approving Ohio EPA's request to modify its SIP to include the revisions at OAC Chapter 3745–14 and to remove OAC Chapter 3745–109 (84 FR 48789).

Under 40 CFR 51.121(i)(4) of the NO_X SIP Call regulations as originally promulgated, where a state's SIP contains control measures for EGUs and large non-EGUs, the SIP must also require these sources to monitor emissions according to the provisions of 40 CFR part 75, which generally entails the use of continuous emission monitoring systems (CEMS). Ohio triggered this requirement by including control measures in their SIP for these types of sources, and the requirement has remained in effect despite the discontinuation of the NO_X Budget Trading Program after the 2008 ozone season. On March 8, 2019, EPA

[1] *EME Homer City Generation, L.P.* v. *EPA,* 696 F.3d 7, 31 (D.C. Cir. 2012) (*EME Homer City I*) (vacating and remanding CSAPR); *EPA* v. *EME Homer City Generation, L.P.,* 572 U.S. 489 (2014) (reversing the D.C. Circuit decision and remanding for further proceedings).

[2] The D.C. Circuit subsequently issued its decision on remand from the Supreme Court, largely affirming CSAPR but remanding certain states budgets to EPA for reconsideration. *EME Homer City Generation, L.P.,* v. *EPA,* 795 F.3d 118 (*EME Homer City II*).

[3] EPA solicited comment on the interim final rule and subsequently issued a final rule affirming the amended compliance schedule after consideration of comments received. 81 FR 13275 (March 14, 2016).

finalized updates to the provision at 40 CFR 51.121(i)(4) to make the inclusion of 40 CFR part 75 monitoring requirements for these sources in SIPs optional rather than mandatory for NO_X SIP Call purposes (84 FR 8422). Under the updated provision, a state's SIP would still need to include some form of emissions monitoring requirements for these types of sources, consistent with the NO_X SIP Call's general enforceability and monitoring requirements at § 51.121(f)(1) and (i)(1), respectively, but states would no longer be required to satisfy these general NO_X SIP Call requirements specifically through the adoption of 40 CFR part 75 monitoring requirements.

After evaluating the various options available following EPA's March 8, 2019, amendments to the NO_X SIP Call regulations, Ohio EPA chose to further revise its rules at OAC Chapter 3745–14 to include alternate monitoring requirements for certain covered sources. These revisions provide a process by which the designated representative for certain NO_X budget units may submit to the Ohio EPA director an application for an installation or operating permit requesting alternative monitoring and reporting requirements, either in the form of 40 CFR part 60 monitoring or in the form of monitoring of heat input and fuel use combined with use of an approved emission factor.

II. What is EPA's analysis of this SIP submission?

Ohio's August 26, 2019, submission requests that EPA update Ohio's SIP to reflect the revised rules at OAC Chapter 3745–14. Additionally, this submission includes a demonstration under Section 110(l) of the CAA intended to show that this SIP revision does not interfere with any applicable CAA requirement.

A. Revised State Rules

Given EPA's revision to the NO_X SIP Call's emissions monitoring requirements, Ohio updated its NO_X SIP Call rules at OAC Chapter 3745–14 to establish emissions monitoring requirements for certain units other than requirements to monitor according to 40 CFR part 75. Specifically, Ohio adopted revisions to OAC rules 3745–14–01, 3745–14–04, and 3745–14–08 with a state-effective date of August 22, 2019. Ohio's August 26, 2019, submission includes a request that EPA approve these updated rules into its SIP.

The state regulations addressing the NO_X SIP Call are established at OAC rules 3745–14–01, 3745–14–03, 3745–14–04, 3745–14–08, 3745–14–11, and 3745–14–12. On September 17, 2019, EPA approved revisions to OAC rule 3745–14–03 concerning NO_X budget permit requirements, and Ohio has not further amended OAC rule 3745–14–03 subsequent to EPA's approval (84 FR 48789). Ohio has also retained OAC rules 3745–14–11 and 3745–14–12 regarding cement kilns and stationary internal combustion engines outside the former trading program. EPA's September 17, 2019, rulemaking also included approval of revisions to OAC rules 3745–14–01, 3745–14–04, and 3745–14–08 pertaining to applicability, the statewide emissions budgets for EGUs and large non-EGUs, and monitoring and reporting under the former trading program. Subsequent to the revisions approved in EPA's September 17, 2019, rulemaking, Ohio further revised OAC rules 3745–14–01, 3745–14–04, and 3745–14–08 to establish alternative monitoring requirements for certain sources, and Ohio's August 26, 2019 submission requests that EPA approve these further revised rules into its SIP.

Specifically, a new provision at OAC rule 3745–14–08 paragraph (H) provides that the Ohio EPA director may approve alternative monitoring and reporting requirements in lieu of the existing requirements at OAC rule 3745–14–08 paragraphs (A) through (G). These alternative requirements shall be based on the best available data, provide for reporting the nature and amount of emissions of a NO_X budget unit, and shall be sufficient to determine compliance with the requirements of OAC Chapter 3745–14. Per OAC rule 3745–14–01 paragraph (C) as approved into Ohio's SIP in EPA's September 17, 2019, rulemaking, the monitoring requirements at OAC rule 3745–14–08 apply only to units that would have been subject to the former NO_X Budget Trading Program and that are not subject to a CSAPR trading program for NO_X emissions pursuant to 40 CFR 52.38, and the revised provisions authorizing alternative monitoring requirements therefore would also apply only to units that are not subject to a CSAPR trading program for NO_X emissions.

The alternative requirements may take one of two forms: Either monitoring and reporting in accordance with 40 CFR part 60, combined with a methodology for determining NO_X mass emissions from 40 CFR part 60 NO_X emission rate data, or monitoring of heat input and fuel use combined with use of an approved emission factor for current operating conditions.

A request under OAC rule 3745–14–08 paragraph (H) for alternative monitoring and reporting requirements must be made by the designated representative of a NO_X budget unit via application for an installation or operating permit. The request must specify which of the two forms is requested. If 40 CFR part 60 monitoring is requested, the application must describe how the amount of NO_X emissions in tons will be determined from the 40 CFR part 60 NO_X emission rate data. If monitoring of heat input and fuel use combined with use of an approved emission factor is requested, then the request must include an analysis evaluating potential emission factors for each fuel type. The analysis of potential emission factors must include an analysis of any historical CEMS data representative of current operating conditions as well as the results of a valid stack test conducted within the two years preceding the application, if available. The application must also describe how monitoring data will be obtained, recorded, and quality-assured and how NO_X emissions will be accounted for during periods of missing or inaccurate data.

If alternative monitoring and reporting is requested to begin within a control period, the application must include a description of the transition process ensuring there will not be gaps in data monitoring and reporting.

The alternative monitoring and reporting requirements must be approved, prior to use, in the applicable installation or operating permit. By April 15 of each year, a report must be made to the Ohio EPA director of actual NO_X emissions for the previous control period, as determined using the approved alternative monitoring procedures. Records must be maintained in accordance with the terms and condition in the installation or operating permit and shall be made available to the Ohio EPA director.

Units using approved emissions factors must conduct stack testing according to an approved test method at least once every five years to demonstrate that the approved emission factors continue to be representative. If an initial application did not include stack test data, an initial stack test must be conducted within 90 days of permit issuance. The results of each stack test must be submitted to Ohio EPA within 30 days of the test. Based on the results of any stack test, Ohio EPA may require submission of a new application to establish more representative emission factors.

Ohio's revisions provide that the rule does not authorize exemptions or alternatives to any 40 CFR part 75 monitoring requirements that might apply to a source under a different legal

authority. The revised rule further states that Ohio EPA will transmit annually to EPA a report of NO_X emissions reported under OAC rule 3745–14–08 paragraph (H), in accordance with the requirements of 40 CFR 51.122(c)(1)(i).

Given the addition of paragraph (H) to OAC rule 3745–14–08, Ohio's revisions also include changes throughout the remainder of OAC rule 3745–14–08 which clarify that sources not adopting approved alternative monitoring and reporting requirements are only subject to the requirements of paragraphs (A) through (G). In OAC rule 3745–14–01, Ohio's revisions clarify references to the revised OAC rule 3745–14–08, and additionally provide updated definitions regarding emissions and emission factors. Ohio's revisions to OAC rule 3745–14–04 provide for a compliance certification process for sources subject to approved alternative monitoring and reporting requirements.

EPA proposes to find that Ohio's revisions to OAC rules 3745–14–01, 3745–14–04, and 3745–14–08 are consistent with Ohio's obligation to demonstrate continued compliance with NO_X SIP Call requirements for large non-EGUs. Under the ongoing requirements of the NO_X SIP Call, the Ohio SIP must: (1) Include enforceable control measures for ozone season NO_X mass emissions from existing and new large EGUs and large non-EGUs and (2) require those sources to monitor and report ozone season NO_X emissions. The emissions monitoring and reporting requirements must be sufficient to ensure compliance with the control measures but there is no mandatory specific methodology; use of 40 CFR part 75 is allowed but not required. See 40 CFR 51.121(f)(2) and (i).

With respect to the NO_X SIP Call requirement that the state have enforceable control measures to limit ozone season NO_X, Ohio is currently subject to the Federal CSAPR Update trading program for ozone season NO_X that addresses these requirements for existing and new EGUs. Because Ohio's non-EGUs are not subject to that CSAPR trading program, the state must meet this requirement for non-EGUs through other SIP provisions. In our September 17, 2019, action, EPA previously approved provisions at OAC rule 3745–14–01 intended to satisfy this requirement for non-EGUs that prohibit ozone season NO_X emissions from existing and new large non-EGUs from exceeding 4,028 tons, the portion of the state's NO_X SIP Call budget assigned to large non-EGUs. Ohio's revisions do not substantively alter the existing provisions at OAC rule 3745–14–01 that address the requirement for enforceable control measures for non-EGUs.[4] Emissions reported to EPA from the state's large non-EGUs for the 2018 ozone season were 543 tons, well below this limit.

As to the requirement for sources to monitor and report ozone season NO_X emissions under the NO_X SIP Call, these SIP revisions would continue to require emissions monitoring from all covered sources, consistent with the NO_X SIP Call's enforceability and monitoring requirements, but certain NO_X budget units would no longer be required to satisfy these requirements specifically through part 75 monitoring requirements. Instead, these revisions would allow large non-EGUs that follow the application process described above to monitor and report their NO_X mass emissions for each ozone season using alternative monitoring requirements.

In EPA's March 8, 2019, rulemaking amending the NO_X SIP Call's monitoring requirements at 40 CFR 51.121(i)(4), EPA observed that, under 40 CFR 51.121(i), the principal criterion for approval of monitoring and reporting requirements for purposes of the NO_X SIP Call following the amendments would be that the requirements must be sufficient to determine whether sources are in compliance with the control measures adopted to achieve the required emissions reductions.[5] EPA noted that for purposes of demonstrating the sufficiency of the monitoring and reporting requirements, a state generally would be able to cite the same types of data (*e.g.,* data indicating substantial compliance margins) that EPA cited to support finalizing the amendments to the NO_X SIP Call regulations.[6] In addition, EPA pointed out the need to consider whether the regulation contains provisions to avoid gaps in required monitoring and whether any monitoring approach that uses emissions factors is designed to avoid any bias toward understatement of emissions.[7]

In Ohio's case, the relevant control measure is the collective cap of 4,028 tons of ozone seasons NO_X emissions established for the set of existing and new non-EGUs in OAC rule 3745–14–01 paragraph (D). As noted above, for the 2018 ozone season, Ohio's large non-EGUs subject to this cap reported collective NO_X emissions of 543 tons, indicating a compliance margin of more than six times recent emissions levels.

While the alternative monitoring requirements available under Ohio's regulation would not provide the same degree of detailed reporting or quality assurance as part 75 monitoring data, and may therefore be more likely to overstate or understate actual emissions to some degree, there is nothing in Ohio's regulation that suggests the data obtained using the alternative monitoring methodologies would be biased toward understatement of emissions. The regulation expressly requires the use of the best available data, it calls for consideration of both historical CEMS data and stack test results when establishing source-specific emission factors, it requires periodic stack testing to verify the continued representativeness of the approved emission factors, and it includes provisions to address cases where an emission factor is found to no longer be representative. Further, the regulation requires procedures to account for emissions during periods of missing or inaccurate data and procedures to avoid data gaps during the transition from 40 CFR part 75 monitoring to alternative monitoring. Given the substantial compliance margin in this instance, EPA believes that the data monitored and reported under Ohio's alternative monitoring requirements would be sufficient to determine whether the state's large non-EGUs are in compliance with their collective emissions cap.

EPA proposes to find that, as revised, OAC rules 3745–14–01, 3745–14–04 and 3745–14–08 meet the state's ongoing obligations under the NO_X SIP Call with respect to existing and new large non-EGUs. Specifically, we propose to find that the revised rules meet the requirement under 40 CFR 51.121(f)(2) for enforceable limits on the units' collective emissions of ozone season NO_X mass emissions and the requirement under 40 CFR 51.121(i)(1) for monitoring sufficient to ensure compliance with those limits. The state's EGUs are currently complying with their analogous NO_X SIP Call requirements through participation in the CSAPR Update trading program for ozone season NO_X.

EPA is proposing to find that Ohio EPA's revisions at OAC Chapter 3745–14 are consistent with applicable requirements under the CAA and the NO_X SIP Call, and EPA is therefore proposing to approve these changes into the Ohio SIP.

[4] As EPA previously determined that the state adequately addressed the NO_X SIP Call requirement that states include enforceable control measures for ozone season NO_X mass emissions from existing and new large EGUs and large non-EGUs, EPA is not reopening for comment the determination made in our September 17, 2019, action.

[5] *See* 84 FR at 8428–29.

[6] *Id.* n.30.

[7] *Id.*

B. Section 110(l) Demonstration

In this action, EPA is proposing to approve Ohio's request to approve updated rules related to the NO_X SIP Call into its SIP. Ohio EPA's submission includes a noninterference demonstration intended to show that its SIP revision is approvable under Section 110(l) of the CAA; such a demonstration is sometimes called an anti-backsliding demonstration. Section 110(l) provides that EPA cannot approve a SIP revision if the revision would interfere with any applicable requirement concerning attainment or reasonable further progress (RFP), or any other applicable requirement of the CAA. Additionally, section 110(l) makes clear that each SIP revision is subject to the requirements of section 110(l). As such, EPA will only approve a SIP revision that removes or modifies control measures in the SIP if the state has demonstrated that such removal or modification would not interfere with attainment and maintenance of the NAAQS, RFP, or any other applicable requirement of the CAA. EPA generally considers whether the SIP revision would worsen, preserve, or improve the status quo in air quality.

For the reasons explained below, we find that EPA's proposed action to update the provisions relating to the NO_X SIP Call satisfies the requirements of CAA section 110(l). As explained above, this action would not alter the NO_X SIP Call emission budgets that limit emissions in the state. The alternate monitoring requirements at OAC Chapter 3745–14 are permanent, enforceable and sufficient to determine whether Ohio's sources are in compliance with the control measures adopted to meet the NO_X SIP Call's emissions requirements. Given continued implementation of SIP requirements governing the unchanged amounts of allowable emissions, accompanied by replacement monitoring requirements sufficient to ensure compliance with the unchanged emissions requirements, this SIP revision is not expected to result in increases in emissions that could interfere with other statutory or regulatory requirements. Importantly, the substitute measure ensures compliance with the existing NO_X SIP Call budgets and thus will preserve the status quo in air quality. For these reasons, we conclude that the revisions will not interfere with attainment and maintenance of the NAAQS, RFP, or any other applicable requirement of the CAA.

For the reasons explained above, EPA is proposing to approve Ohio EPA's SIP submission under section 110(l) of the CAA.

III. What action is EPA taking?

EPA is proposing to approve Ohio EPA's request to modify its SIP to include the revisions at OAC Chapter 3745–14.

IV. Incorporation by Reference

In this rule, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference OAC rules 3745–14–01, 3745–14–04, and 3745–14–08, with a state-effective date of August 22, 2019. EPA has made, and will continue to make, these documents generally available through *www.regulations.gov* and at the EPA Region 5 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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, 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 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).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where 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 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).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: October 17, 2019.

Cathy Stepp,

Regional Administrator, Region 5.

[FR Doc. 2019–23704 Filed 11–1–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2019–0528; FRL–10001–68–Region 9]

Air Plan Approval; California; Northern Sierra Air Quality Management District; Reasonably Available Control Technology

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Northern Sierra Air Quality Management District (NSAQMD or ''District'') portion of the California

State Implementation Plan (SIP) under the Clean Air Act (CAA or ''the Act''). This revision concerns the District's demonstration regarding reasonably available control technology (RACT) requirements for the 2008 8-hour ozone national ambient air quality standard (NAAQS or ''standards'') in the Western Nevada County ozone nonattainment area, which is under the jurisdiction of the NSAQMD. We are taking comments on this proposal and plan to follow with a final action.

DATES: Any comments must arrive by December 4, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2019–0528 at *https://www.regulations.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Stanley Tong, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 947–4122 or by email at *tong.stanley@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

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I. The State's Submittal

A. What document did the State submit?

On March 26, 2018, the NSAQMD adopted the ''Reasonably Available Control Technology (RACT) State Implementation Plan (SIP) Revision for Western Nevada County 8-Hour Ozone Nonattainment Area'' (''*2018 RACT SIP*''), and on June 7, 2018, the California Air Resources Board (CARB) submitted it to the EPA for approval as a revision to the California SIP. On November 29, 2018, the EPA determined that the submittal for the NSAQMD's *2018 RACT SIP* met the completeness criteria in 40 CFR part 51 Appendix V, which must be met before formal EPA review.

B. Are there other versions of this document?

There are no previous versions of this document in the NSAQMD portion of the California SIP for the 2008 8-hour ozone NAAQS.

C. What is the purpose of the submitted document?

Volatile organic compounds (VOCs) and oxides of nitrogen (NO_X) contribute to the production of ground-level ozone, smog, and particulate matter, which harm human health and the environment. Section 110(a) of the CAA requires states to submit regulations that control VOCs and NO_X emissions. CAA sections 182(b)(2) and (f) require that SIPs for areas designated nonattainment for the ozone NAAQS and classified as Moderate or above implement RACT for any source covered by a Control Techniques Guidelines (CTG) document and for any major source of VOCs or NO_X.

The NSAQMD is subject to this RACT SIP requirement, as the District regulates the Western Nevada County, California, ozone nonattainment area, which was classified as Moderate for the 2008 8-hour ozone NAAQS on May 4, 2016. See 81 FR 26697, 26713. Therefore, to satisfy sections 182(b)(2) and (f) of the Act, the NSAQMD must, at a minimum, adopt RACT-level controls for all sources covered by a CTG document and for all major non-CTG sources of VOCs or NO_X within the ozone nonattainment area that it regulates.

The EPA issued a final rule on August 23, 2019, in which it reclassified Western Nevada County as ''Serious'' nonattainment for the 2008 ozone NAAQS. See 84 FR 44238, 44250. NSAQMD adopted its RACT SIP in 2018, when it was still classified as a Moderate ozone nonattainment area. However, in anticipation of the area being reclassified as a Serious nonattainment area for the 2008 ozone NAAQS, the NSAQMD's *2018 RACT SIP* evaluated whether the District had any major VOC/NO_X sources emitting at least 50 tons per year (tpy), which is the major source threshold for ozone precursors for Serious ozone nonattainment areas.[1]

Section III.D of the preamble to the EPA's final rule to implement the 2008 8-hour ozone NAAQS (80 FR 12264, March 6, 2015) discusses RACT requirements. It states in part that RACT SIPs must contain adopted RACT regulations, certifications where appropriate that existing provisions are RACT, and/or negative declarations that no sources in the nonattainment area are covered by a specific CTG. Id. at 12278. It also provides that states must submit appropriate supporting information for their RACT submissions as described in the EPA's implementation rule for the 1997 ozone NAAQS. See id. and 70 FR 71612, 71652 (November 29, 2005). The *2018 RACT SIP,* including its negative declarations, provide the NSAQMD's analysis of its compliance with CAA section 182 RACT requirements for the 2008 8-hour ozone NAAQS.

The EPA's technical support document (TSD) for this action has more information about the District's *2018 RACT SIP* submittal and the EPA's evaluation thereof.

II. The EPA's Evaluation and Proposed Action

A. How is the EPA evaluating the submitted document?

Generally, SIP rules must require RACT for each category of sources covered by a CTG document as well as each major source of VOCs or NO_X in ozone nonattainment areas classified as Moderate or above (see CAA sections 182(b)(2) and (f), and 40 CFR 51.1112(a) and (b)). The NSAQMD regulates an ozone nonattainment area classified as Serious for the 2008 8-hour NAAQS (40 CFR 81.305) so the District's rules must implement RACT. Because Western Nevada County was recently reclassified as Serious nonattainment for the 2008 8-hour ozone NAAQS, and because NSAQMD's 2018 RACT SIP provided an

[1] Any stationary source that emits or has the potential to emit at least 50 tpy of VOCs or NO_X is a major stationary source in a Serious ozone nonattainment area (CAA section 182(b)(2), (f), and 302(j)).

analysis of RACT that addresses the requirements for a Serious area as well as a Moderate area in anticipation of this reclassification, we evaluated the *2018 RACT SIP* submittal to determine whether it met RACT requirements for a Serious ozone nonattainment area as well those for a Moderate ozone nonattainment area. Specifically, as part of our evaluation of the *2018 RACT SIP,* we evaluated NSAQMD's *2018 RACT SIP* using the 50 tpy threshold for major stationary sources of VOC or NO_X in Serious ozone nonattainment areas.

As part of their RACT submittals, States should also submit for SIP approval negative declarations for CTG source categories for which the States have not adopted CTG-based regulations because they have no sources above the CTG-recommended applicability threshold, regardless of whether such negative declarations were made for an earlier SIP.[2] To do so, the RACT submittals should provide reasonable assurance that no sources subject to the CTGs' requirements currently exist in the relevant ozone nonattainment area.

With respect to the NSAQMD, the District's analysis must demonstrate that each major source of VOCs or NO_X in the Western Nevada County ozone nonattainment area is covered by a RACT-level rule. In addition, for each CTG source category, the District must either demonstrate that a RACT-level rule is in place, or submit a negative declaration. Guidance and policy documents that we use to evaluate CAA section 182 RACT requirements include the following:

1. ''State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990,'' 57 FR 13498 (April 16, 1992); 57 FR 18070 (April 28, 1992).

2. EPA Office of Air Quality Planning and Standards, ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations,'' May 25, 1988 (''the Bluebook,'' revised January 11, 1990).

3. ''State Implementation Plans; Nitrogen Oxides Supplement to the General Preamble; Clean Air Act Amendments of 1990 Implementation of Title I; Proposed Rule,'' (''the NO_X Supplement''), 57 FR 55620, (November 25, 1992).

4. Memorandum dated May 18, 2006, from William T. Harnett, Director, Air Quality Policy Division, to Regional Air Division Directors, Subject: ''RACT Qs & As—Reasonably Available Control Technology (RACT): Questions and Answers.''

5. ''Final Rule to Implement the 8-hour Ozone National Ambient Air Quality Standard—Phase 2,'' 70 FR 71612 (November 29, 2005).

6. ''Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements,'' 80 FR 12264 (March 6, 2015).

B. Does the document meet the evaluation criteria?

The NSAQMD's *2018 RACT SIP* provides the District's demonstration that the applicable SIP for the Western Nevada County ozone nonattainment area, which is under the jurisdiction of the NSAQMD, satisfies CAA section 182 RACT requirements for the 2008 8-hour ozone NAAQS. The District's conclusion is based on its analysis of SIP-approved requirements that apply to the following: (1) Source categories for which a CTG has been issued, and (2) major non-CTG stationary sources of VOC or NO_X emissions.

With respect to CTG source categories, the NSAQMD determined that it only had sources subject to the CTGs covering gasoline service stations and vapor recovery operations, gasoline tank truck vapor tightness, and cutback asphalt. The District also stated that it no longer had sources subject to the miscellaneous metal coating CTG, but ''. . . would like to keep the rule in the SIP for the 2008 standard in case a new source opens . . .'' For each of these CTG source categories, the District's submittal provided an analysis to support the District's finding that a District rule previously approved by the EPA into the SIP as RACT for Western Nevada County remains RACT for the 2008 8-hour ozone NAAQS. Specifically, Section 5 of NSAQMD's *2018 RACT SIP* provides a short discussion of the following District rules and why they continue to implement RACT: Rule 214, ''Phase I Vapor Recovery Requirements;'' Rule 215, ''Phase II Vapor Recovery System Requirements;'' Rule 227, ''Cutback and Emulsified Asphalt Paving Materials;'' and Rule 228, ''Surface Coating of Metal Parts and Products.'' We reviewed NSAQMD's evaluation of its rules addressing the CTG source categories that are subject to RACT[3] in Western Nevada County. We agree that the District's rules are generally consistent with the CTGs and recently adopted rules in other air districts, and therefore satisfy CAA RACT requirements for the 2008 8-hour ozone NAAQS. With respect to the CTG for Miscellaneous Metal and Plastic Parts Coating, the *2018 RACT SIP* states that the District has no sources subject to Tables 3–6 of this CTG, and is adopting negative declarations for coatings covered by those tables. The *2018 RACT SIP* also states that the only source in the Western Nevada County ozone nonattainment area that was subject to the CTG's Table 2 ''Metal Parts and Products'' has closed, but the District did not adopt a negative declaration for the category sources subject to Table 2, and stated its preference to leave the applicable rule—Rule 228—in the RACT SIP. We agree that Rule 228's VOC content limits are consistent with Table 2 of the CTG and the rule continues to meet RACT.

Where there are no existing sources covered by a particular CTG document, states may, in lieu of adopting RACT requirements for those sources, adopt negative declarations certifying that there are no such sources in the relevant nonattainment area. States may also use negative declarations to certify that there are no major non-CTG sources subject to RACT, where applicable. NSAQMD's *2018 RACT SIP* contains a table listing the EPA's CTGs and annotates those CTGs for which the District is adopting a negative declaration, indicating that the District has no sources subject to the applicable CTG for the 2008 8-hour ozone NAAQS. These negative declarations are listed in Table 1 below. The District concludes that it has no sources subject to the relevant CTGs, based on a review of its permit files and emission inventory, as well as business listings and county planning records.

[2] 57 FR 13498, 13512 (April 16, 1992).

[3] The NSAQMD rules and corresponding CTGs are as follows. District Rule 214, ''Phase I Vapor Recovery Requirements'', corresponds to the CTGs entitled ''Design Criteria for Stage I Vapor Control Systems—Gasoline Service Stations'' (EPA–450/R–75–102) and ''Control of Volatile Organic Compound Leaks from Gasoline Tank Trucks and Vapor Collection Systems'' (EPA–450/2–78–051). District Rule 227, ''Cutback and Emulsified Asphalt Paving Materials,'' corresponds to the CTG entitled ''Control of Volatile Organic Compounds from Use of Cutback Asphalt'' (EPA–450/2–77–37). District Rule 228, ''Surface Coating of Metal Parts and Products'', corresponds to the source category in Table 2 of the CTG entitled ''Control of Volatile Organic Emissions from Existing Stationary Sources, Volume VI: Surface Coating of Miscellaneous Metal Parts and Products, and Control Techniques Guidelines for Miscellaneous Metal and Plastic Parts Coatings'' (EPA–453/R–08–003). We note that while NSAQMD also reviewed Rule 215, ''Phase II Vapor Recovery System Requirements,'' as meeting RACT, and the EPA has approved the rule as meeting RACT, the EPA has not published a CTG for vehicle refueling operations.

In addition, the *2018 RACT SIP* states ''there are no major sources (that emit or have the potential to emit 50 tons or more per year) of ozone precursors located in the nonattainment area. . . .'' [4] In another portion of its *2018 RACT SIP,* NSAQMD states ''[t]he largest stationary source of ozone precursors in the Western Nevada County ozone nonattainment area is currently a gas station that emits under 2 tons of precursors per year.'' [5]

We reviewed CARB's emissions inventory for the NSAQMD and also performed a general internet search for potential sources subject to selected CTGs in Western Nevada County. Based on our review, we agree with the District's negative declarations in its *2018 RACT SIP.* We found that CARB's emissions inventory for the years 2014–2017 showed that the largest VOC and NO_X emitting stationary source in the Western Nevada County ozone nonattainment area emitted less than 2 tpy of VOC and NO_X. Our TSD has more information on our evaluation of the *2018 RACT SIP.* Table 1 below summarizes the CTG categories for which NSAQMD has provided negative declarations.

TABLE 1—NSAQMD NEGATIVE DECLARATIONS

EPA document No.	Title
EPA–450/2–77–008	Surface Coating of Cans.
EPA–450/2–77–008	Surface Coating of Coils.
EPA–450/2–77–008	Surface Coating of Paper.
EPA–450/2–77–008	Surface Coating of Fabric.
EPA–450/2–77–008	Surface Coating of Automobiles and Light-Duty Trucks.
EPA–450/2–77–022	Solvent Metal Cleaning.
EPA–450/2–77–025	Refinery Vacuum Producing Systems, Wastewater Separators, and Process Unit Turnarounds.
EPA–450/2–77–026	Tank Truck Gasoline Loading Terminals.
EPA–450/2–77–032	Surface Coating of Metal Furniture.
EPA–450/2–77–033	Surface Coating of Insulation of Magnet Wire.
EPA–450/2–77–034	Surface Coating of Large Appliances.
EPA–450/2–77–035	Bulk Gasoline Plants.
EPA–450/2–77–036	Storage of Petroleum Liquids in Fixed-Roof Tanks.
EPA–450/2–78–029	Manufacture of Synthesized Pharmaceutical Products.
EPA–450/2–78–030	Manufacture of Pneumatic Rubber Tires.
EPA–450/2–78–032	Factory Surface Coating of Flat Wood Paneling.
EPA–450/2–78–033	Graphic Arts-Rotogravure and Flexography.
EPA–450/2–78–036	Leaks from Petroleum Refinery Equipment.
EPA–450/2–78–047	Petroleum Liquid Storage in External Floating Roof Tanks.
EPA–450/3–82–009	Large Petroleum Dry Cleaners.
EPA–450/3–83–006	Leaks from Synthetic Organic Chemical Polymer and Resin Manufacturing Equipment.
EPA–450/3–83–007	Leaks from Natural Gas/Gasoline Processing Plants.
EPA–450/3–83–008	Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins.
EPA–450/3–84–015	Air Oxidation Processes in Synthetic Organic Chemical Manufacturing Industry.
EPA–450/4–91–031	Reactor Processes and Distillation Operations in Synthetic Organic Chemical Manufacturing Industry.
EPA–453/R–96–007	Wood Furniture Manufacturing Operations.
EPA–453/R–94–032; 61 FR 44050; 8/27/96.	ACT Surface Coating at Shipbuilding and Ship Repair Facilities Shipbuilding and Ship Repair Operations (Surface Coating).
EPA–453/R–97–004; 59 FR 29216; 6/06/94.	Aerospace MACT and Aerospace (CTG & MACT).
EPA–453/R–06–001	Industrial Cleaning Solvents.
EPA–453/R–06–002	Offset Lithographic Printing and Letterpress Printing.
EPA–453/R–06–003	Flexible Package Printing.
EPA–453/R–06–004	Flat Wood Paneling Coatings.
EPA 453/R–07–003	Paper, Film, and Foil Coatings.
EPA 453/R–07–004	Large Appliance Coatings.
EPA 453/R–07–005	Metal Furniture Coatings.
EPA 453/R–08–003	Miscellaneous Metal Parts and Plastic Parts Coatings, Tables 3–6.
EPA 453/R–08–004	Fiberglass Boat Manufacturing Materials.
EPA 453/R–08–005	Miscellaneous Industrial Adhesives.
EPA 453/R–08–006	Automobile and Light-Duty Truck Assembly Coatings.
EPA 452/B16–001	Oil and Natural Gas Industry.
—N/A—	Major non-CTG VOC sources.
—N/A—	Major non-CTG NO_X sources.

C. The EPA's Recommendations To Further Improve the RACT SIP

Our TSD includes recommendations to improve the RACT SIP for the upcoming 2015 8-hour ozone NAAQS. These recommendations include, among other things, that the District consider amending Rule 214, ''*Phase 1 Vapor Recovery*'', to require recordkeeping for facilities that use the rule's throughput exemption threshold, and that the District evaluate whether additional negative declarations can be adopted for the cutback/emulsified asphalt and miscellaneous metal and plastic parts CTGs.

D. Public Comment and Proposed Action

As authorized in section 110(k)(3) of the Act, the EPA proposes to fully approve the *2018 RACT SIP,* including the negative declarations listed in Table 1, because it fulfills the RACT SIP requirements under CAA sections

[4] *2018 RACT SIP,* 1, 5, and 12.

[5] *Id.* at 1.

182(b) and (f) and 40 CFR 51.1112(a) and (b) for the 2008 ozone NAAQS. We will accept comments from the public on this proposal until December 4, 2019. If we take final action to approve the submitted document, our final action will incorporate this document into the federally enforceable SIP.

III. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act 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, if they meet the criteria of the Act. Accordingly, this proposed action merely proposes to approve state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed 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 disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, 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 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).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Volatile organic compounds.

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

Dated: October 21, 2019.

Deborah Jordan,

Acting Regional Administrator, Region IX.

[FR Doc. 2019–23828 Filed 11–1–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2019–0494; FRL–10000–54]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances (19–4.F)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 26 chemical substances which were the subject of premanufacture notices (PMNs). Five of these chemical substances are subject to Orders issued by EPA pursuant to TSCA, and the remaining 21 of these chemical substances received a ''not likely to present an unreasonable risk'' determination pursuant to TSCA. This action would require persons who intend to manufacture (defined by statute to include import) or process any of these 26 chemical substances for an activity that is proposed as a significant new use to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the use, under the conditions of use for that chemical substance, within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required by that determination.

DATES: Comments must be received on or before December 4, 2019.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2019–0494, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–9232; email address: *moss.kenneth@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this proposed rule. The following list of North American 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:

- Manufacturers or processors of one or more subject chemical substances

(NAICS codes 325 and 324110), *e.g.,* chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to final SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after December 4, 2019 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see 40 CFR 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. Background

A. What action is the Agency taking?

EPA is proposing these SNURs under TSCA section 5(a)(2) for chemical substances that were the subject of PMNs. These proposed SNURs would require persons to notify EPA at least 90 days before commencing the manufacture or processing of a chemical substance for any activity proposed as a significant new use. Receipt of such notices would allow EPA to assess risks and, if appropriate, to regulate the significant new use before it may occur. Additional background regarding SNURs is more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** issue of April 24, 1990 (55 FR 17376). Consult that preamble for further general information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

B. What is the Agency's authority for taking this action?

TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the proposed rule, recordkeeping requirements, and exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. Pursuant to 40 CFR 721.1(c), persons subject to SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A) (15 U.S.C. 2604(a)(1)(A)). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1) (15 U.S.C. 2604(b) and 2604(d)(1)), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the use is not likely to present an unreasonable risk of injury under the conditions of use for the chemical substance or take such regulatory action as is associated with an alternative determination before the manufacture or processing for the significant new use can commence. In the case of a determination other than not likely to present unreasonable risk, the applicable review period must also expire before manufacturing or processing for the new use may commence. If EPA determines that the use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's findings.

III. Significant New Use Determination

TSCA section 5(a)(2) states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In determining significant new uses for the 26 chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances and potential human exposures and environmental releases that may be associated with the substances, in addition to the factors in TSCA section 5(a)(2). Consistent with TSCA section 5(f)(4), for the five chemical substances subject to an order under TSCA section 5(e), EPA is proposing to identify any use not conforming to the restrictions of the order as a significant new use. For the 21 chemical substances that EPA has determined ''not likely'' to present an unreasonable risk under the conditions of use, EPA is proposing to identify other circumstances that, while not reasonably foreseen, would warrant further EPA review before manufacture or processing for such a use is commenced.

IV. Substances Subject to This Proposed Rule

EPA is proposing significant new use and recordkeeping requirements for 26 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Basis for the SNUR or basis for the TSCA 5(e) Order.
- Potentially Useful Information. This is information identified by EPA that

would help characterize the potential health and/or environmental effects of the chemical substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by the SNUR.

• CFR citation assigned in the regulatory text section of the proposed rule. The regulatory text section of each proposed rule specifies the activities that would be designated as significant new uses. Certain new uses, including exceedance of production volume limits (*i.e.,* limits on manufacture volume) and other uses designated in this proposed rule, may be claimed as CBI.

These proposed rules include five PMN substances that are subject to Orders issued under TSCA section 5(e)(1)(A), as required by the determinations made under section 5(a)(3)(B). Those Orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The proposed SNURs would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying Orders, consistent with TSCA section 5(f)(4).

These proposed rules also include 21 PMN substances that received ''not likely to present an unreasonable risk'' determination in TSCA section 5(a)(3)(c). However, during the course of these reviews, EPA identified concerns for certain health and/or environmental risks if the chemicals were not used following the limitations identified by the submitters in the notices, but the TSCA section 5(a)(3)(C) determinations did not deem such uses as reasonably foreseen. The proposed SNURs would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to those same limitations.

The chemicals subject to these proposed SNURs are as follows:

PMN Number: P–16–548

Chemical Name: Triarylsulfonium salt (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: July 22, 2019.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the PMN substance will be as a resin catalyst. Based on physical/chemical properties of the PMN substance (as described in the New Chemical Program's PBT category at 64 FR 60194; November 1999), the PMN substance is a potentially persistent, bioaccumulative, and toxic (PBT) chemical. EPA estimates that that PMN substance will persist in the environment for more than 2 months and estimates a bioaccumulation factor of greater than or equal to 1,000. Based on comparison to structurally analogous chemical substances, the estimated physical/chemical properties of the PMN, and test data for the PMN substance, EPA has identified concerns for eye irritation, systemic, developmental, blood, and reproductive effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Refraining from domestic manufacture in the United States (*i.e.,* import only);

2. Use of the PMN substance only for the confidential use specified in the Order;

3. No manufacture (including import) of the PMN substance beyond the confidential annual manufacture volume specified in the Order;

4. Refraining from processing or using the PMN substance in any manner that generates a mist, vapor, or aerosol; and

5. No release of the PMN substance into the waters of the United States.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the TSCA section 5(e) Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. EPA has determined that the results of specific target organ toxicity and reproductive/developmental toxicity testing would help characterize the potential health effects of the PMN substance. Although the TSCA section 5(e) Order does not require this information, the TSCA section 5(e) Order's restrictions remain in effect until the TSCA section 5(e) Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR Citation: 40 CFR 721.11383.

PMN Numbers: P–17–312, P–17–313, P–17–314, P–17–315, P–17–316, and P–17–317

Chemical Names: Organic acid, compds. with bisphenol A-epichlorohydrin-polypropylene glycol diglycidyl ether polymer-disubstituted amine-disubstituted polypropylene glycol reaction products (generic) (P–17–312); Phenol, 4,4′-(1-methylethylidene)bis-, polymer with 2-(chloromethyl)oxirane and alpha-(2-oxiranylmethyl)-omega-(2-oxiranylmethoxy)poly[oxy(methyl-1,2-ethanediyl)], reaction products with disubstituted amine and disubstituted polypropylene glycol, organic acid salts (generic) (P–17–313); Organic acid, 2-substituted-, compds. with bisphenol A-epichlorohydrin-polypropylene glycol diglycidyl ether polymer-disubstituted aminedisubstituted polypropylene glycol reaction products (generic) (P–17–314); Phenol, 4,4′-(1-methylethylidene)bis-, polymer with alpha-(2-substituted-methylethyl)-omega-(2-substituted-methylethoxy)poly[oxy(methyl-1,2-ethanediyl)], 2-(chloromethyl)oxirane and alpha-(2-oxiranylmethyl)-omega-(2-oxiranylmethoxy)poly[oxy(methyl-1,2-ethanediyl)], alkylphenyl ethers, reaction products with disubstituted amine, organic acid salts (generic) (P–17–315); Organic acid, compds. with bisphenol A-epichlorohydrin-disubstituted polypropylene glycol-polypropylene glycol diglycidyl ether polymer alkylphenyl ethers-disubstituted amine reaction products (generic) (P–17–316); Organic acid, compds. with bisphenol A-epichlorohydrin-polypropylene glycol diglycidyl ether polymer-disubstituted polypropylene glycol reaction products (generic) (P–17–317).

CAS Numbers: Not available.

Basis for action: The PMNs state that the generic (non-confidential) use of the substances will be as additives for electrocoat. Based on the estimated physical/chemical properties of the PMN substances, comparison with structurally analogous substances, and Structural Activity Relationships (SAR) analysis on analogous polycationic polymers, EPA has identified concerns for lung effects, nasal epithelial damage, skin and eye irritation, and aquatic toxicity if the chemical substances are not used following the limitations noted. The conditions of use of the PMN substances as described in the PMNs include the following protective measures:

1. No modification of the manufacturing, processing, or use of the PMN substances that result in the

generation of a dust, mist, or aerosol; and

2. No release of a manufacturing, processing, or use stream associated with any use of the PMN substance into the waters of the United States exceeding a surface water concentration of 78 ppb.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health and environmental effects of the PMN substances if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of pulmonary effects, skin irritation/corrosion, eye damage, and acute aquatic toxicity testing would help characterize the potential health effects of the PMN substances.

CFR Citations: 40 CFR 721.11384 (P–17–312), 40 CFR 721.11385 (P–17–313), 40 CFR 721.11386 (P–17–314), 40 CFR 721.11387 (P–17–315), 40 CFR 721.11388 (P–17–316), and 40 CFR 721.11389 (P–17–317).

PMN Numbers: P–17–398, P–17–399, P–18–1, and P–18–28

Chemical names: Branched cyclic and linear hydrocarbons from plastic depolymerization (generic) (P–17–398), Alkane, alkene, styrenic compounds derived from plastic depolymerization (generic) (P–17–399), Carbon compound derived from plastic depolymerization (generic) (P–18–1), and Branched cyclic and linear hydrocarbons from plastic depolymerization (generic) (P–18–28).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: June 10, 2019.

Basis for TSCA section 5(e) Order: The PMNs state that the use of P–17–398 and P–17–399 will be as a refinery feedstock or fuel blending additive, the generic use of P–18–1 will be as an additive, and the use of P–18–28 will be as a chemical feedstock. Based on the physical/chemical properties of the PMN substances and comparison to structurally analogous chemical substances, EPA has identified concerns for neurological impairment, and hematological effects including aplastic anemia and acute myelogenous leukemia for PMN substance P–18–28. There is concern for lung effects for P–18–1, if respirable, based on the respirable, poorly soluble particles category. Based on SAR analysis on analogous substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb for P–17–398 and P–17–399, and 15 ppb for P–18–28. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health and the environment. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substances are or will be produced in substantial quantities and that the substances either enter or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substances. To protect against these risks, the Order requires:

1. Refraining from manufacturing, processing, or using P–17–398 and P–17–399 other than as a refinery feedstock or a fuel blending additive and refrain from manufacturing, processing, and using P–18–28 other than as a chemical feedstock or a fuel blending additive;

2. Manufacture of P–18–1 via the enclosed manufacturing process described in the PMN; and

3. Manufacture of P–18–1 according to the particle sizes described in the PMN: 1% or less of the particles at less than 75 microns.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health and environmental effects of the PMN substances may be potentially useful in support of a request by the PMN submitter to modify the TSCA section 5(e) Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. EPA has determined that the results of additional particle size characterization testing for P–18–1 and acute and chronic aquatic toxicity testing for P–17–398, P–17–399, and P–18–28 would help EPA determine the potential human and environmental effects of the PMN substances. Although the TSCA section 5(e) Order does not require this information, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citations: 40 CFR 721.11390 (P–17–398), 40 CFR 721.11391 (P–17–399), 40 CFR 721.11392 (P–18–1), and 40 CFR 721.11393 (P–18–28).

PMN Number: P–18–9

Chemical Name: Phosphonic acid, dimethyl ester, polymer with alkyl diols (generic).

CAS Number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as a lubricant additive. Based on estimated physical/chemical properties of the PMN substance, test data on the PMN substance, comparison to structurally analogous chemical substances, and SAR analysis of test data on analogous esters, EPA has identified concerns for gastrointestinal and kidney effects, reproductive/developmental toxicity, and aquatic toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No release of a manufacturing, processing, or use stream associated with any use of the PMN substance into the waters of the United States exceeding a surface water concentration of 300 ppb; and

2. No manufacture, process, or use of the PMN substance that generates a dust, mist, or aerosol.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health and environmental effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of aquatic toxicity, specific target organ toxicity, and reproductive/developmental toxicity testing would help characterize the potential health and environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.11394.

PMN Number: P–18–11

Chemical Name: 1H-Imidazole, 1,2,4,5-tetramethyl-.

CAS Number: 1739-83-9.

Basis for action: The PMN states that the use of the PMN substance will be as a chemical intermediate in the synthesis of a polymer. Based on estimated physical/chemical properties of the PMN substance, test data on analogous chemical substances, comparison to structurally analogous chemical substances, and SAR analysis of test data on analogous pyrroles/diazoles, EPA has identified concerns for irritation and corrosion to all tissues,

developmental effects, liver toxicity, and aquatic toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. Refraining from domestic manufacture in the United States (*i.e.,* import only);

2. No release of a manufacturing, processing, or use stream associated with any use of the PMN substance into the waters of the United States exceeding a surface water concentration of 7 ppb; and

3. No use of the PMN substance other than as a chemical intermediate.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health and environmental effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of skin corrosion, developmental/reproductive toxicity, specific target organ toxicity, and aquatic toxicity testing would help characterize the potential health and environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.11395.

PMN Number: P–18–170

Chemical Name: 1-Propanaminium, N,N′-(oxydi-2,1-ethanediyl)bis[3-chloro-2-hydroxy-N,N-dimethyl-, chloride (1:2).

CAS Number: 96320–92–2.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be for use in textile treatment. Based on the physical/chemical properties of the PMN substance, comparison of structurally analogous chemical substances, and SAR analysis on cationic surfactants, EPA has identified concerns for surfactant effects on the lungs, developmental effects, mutagenicity, carcinogenicity, systemic toxicity, skin and respiratory sensitization, liver and kidney toxicity and aquatic toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacturing, processing, or use of the PMN substance that results in inhalation exposures; and

2. No release of a manufacturing, processing, or use stream associated with any use of the PMN substance into the waters of the United States exceeding a surface water concentration of 164 ppb.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health and environmental effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific target organ toxicity, reproductive/developmental toxicity, and chronic aquatic toxicity testing would help characterize the potential health and environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.11396.

PMN Number: P–18–185

Chemical Name: Fatty acid, polymer with alkanedioic acid dialkyl ester, hydroxyl alkyl substituted alkanediol, substituted carbomonocycle and alkylol substituted alkane (generic). Polymer exemption flag: The chemical must be manufactured such that it meets the polymer exemption criteria as described under 40 CFR 723.250(e)(1), in addition to meeting the definition of polymer at 40 CFR 723.250(b).

CAS Number: Not available.

Basis for action: The PMN states that the use of the PMN substance will be as an adhesion-enhancing resin for wood applications for industrial and commercial use. Based on estimated physical/chemical properties of the PMN substance and comparison to structurally analogous chemical substances, EPA has identified concerns for developmental and reproductive effects if the chemical substance is not used following the limitation noted. The conditions of use of the PMN substance as described in the PMN include the following protective measure:

- No use of the PMN substance in a consumer product.

The proposed SNUR would designate as a ''significant new use'' the absence of this protective measure.

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that reproductive/developmental toxicity testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11397.

PMN Numbers: P–18–190 and P–18–191

Chemical Names: 2,5-Furandione, polymer with ethenylbenzene, 4-hydroxy-substituted butyl amide, polymers with epichlorohydrin and trimethylolpropane, sodium salts (generic) (P–18–190); 2,5-Furandione, polymer with ethenylbenzene, 4-hydroxy-substitutedbutyl [3-[2-[1-[[(substitutedphenyl)amino]carbonyl]-2-oxopropyl]diazenyl]phenyl]methyl amide, polymers with epichlorohydrin and trimethylolpropane, sodium salts (generic) (P–18–191).

CAS Numbers: Not available.

Basis for action: The PMNs state that the use of the substances will be as a pigment dispersing aid for pigments in inkjet printing inks. Based on the estimated physical/chemical properties, high pH, chelating potential of the polyanionic groups and comparison with structurally analogous chemical substances, EPA has identified concerns for developmental and blood effects, and eye, skin, and lung irritation if the chemical substances are not used following the limitation noted. The conditions of use of the PMN substances as described in the PMNs include the following protective measure:

- Use of the PMN substances only as pigment dispersing aids for pigments in inkjet printing inks.

The proposed SNUR would designate as a ''significant new use'' the absence of this protective measure.

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health effects of the PMN substances if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of reproduction/developmental toxicity, skin irritation, and eye damage testing would help characterize the potential health effects of the PMN substances.

CFR Citations: 40 CFR 721.11398 (P–18–190) and 40 CFR 721.11399 (P–18–191).

PMN Number: P–18–223

Chemical Name: Alkane, bis(alkoxymethyl)-dimethyl- (generic).

CAS Number: Not available.

Basis for action: The PMN states that the use of the PMN substance will be as a selectivity improver for catalysts used in polyolefin production. Based on estimated physical/chemical properties, comparison to structurally analogous chemical substances, test data on the PMN substance, and SAR analysis on analogous neutral organics, EPA has

identified concerns for eye irritation, systemic and developmental toxicity, neurotoxicity and aquatic toxicity if the chemical substance is not used following the limitation noted. The conditions of use of the PMN substance as described in the PMN include the following protective measure:

• No manufacture of the PMN substance beyond the confidential annual production volume specified in the PMN.

The proposed SNUR would designate as a ''significant new use'' the absence of this protective measure.

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health and environmental effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of toxicokinetics, specific organ toxicity, irritation, neurotoxicity, systemic toxicity, reproductive/developmental toxicity, and aquatic toxicity testing would help characterize the potential health and environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.11400.

PMN Number: P–18–285

Chemical Name: Butanedioic acid, 2-methylene-, polymer with 2-methyl-2-[(1-oxo-2-propen-1-yl)amino]-1-propanesulfonic acid, sodium zinc salt.

CAS Number: 2220235–78–7.

Basis for action: The PMN states that the use of the PMN substance will be for odor neutralization for pet litter and cleaning/deodorizing hard surfaces, fabrics, skin and hair, odor neutralization for air care, and odor neutralization for waste processing and solid waste management in paper, oil, gas, mining, agriculture, and food and municipal industries. Based on SAR analysis on analogous polyanionic polymers, EPA has identified concerns for aquatic toxicity if the chemical substance is not used following the limitation noted. The conditions of use of the PMN substance as described in the PMN include the following protective measure:

• No release of a manufacturing, processing, or use stream associated with any use of the PMN substance into the waters of the United States exceeding a surface water concentration of 143 ppb.

The proposed SNUR would designate as a ''significant new use'' the absence of this protective measure.

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the environmental effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of chronic aquatic toxicity testing would help characterize the potential environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.11404.

PMN Number: P–18–300

Chemical Name: Heteromonocycle, alkenoic 1:1 salt, polymer with alpha-(2-methyl-1-oxo-2-propen-1-y)l-omega-methoxypoly(oxy-1,2-ethanediyl) and methyl-alkenoic acid (generic).

CAS Number: Not available.

Basis for action: The PMN states that the use of the PMN substance will be as an additive for automatic dishwashing detergent. Based on the estimated physical/chemical properties of the PMN substance, comparison with structurally analogous chemical substances, and available data on the new chemical substance, EPA has identified concerns for lung effects if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacturing, processing, or use that results in particles less than 50 microns; and

2. No use that results in consumer inhalation or dermal exposure and use only in sealed, single-use packets.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of pulmonary effects, specific target organ effects, and developmental/reproductive toxicity testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11405.

PMN Number: P–18–394

Chemical Name: Substituted benzylic ether polyethylene glycol alkyl ether derivative (generic).

CAS Number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as a chemical intermediate. Based on estimated physical/chemical properties of the PMN substance, comparison to structurally analogous chemical substances, and test data on the PMN substance, and SAR analysis on analogous nonionic surfactants, EPA has identified concerns for ocular, lung and mucous membrane irritation, lung effects, skin and respiratory sensitization, systemic effects, neurotoxicity, immunotoxicity, and aquatic toxicity if the chemical substance is not used following the limitation noted. The condition of use of the PMN substance as described in the PMN includes the following protective measures:

1. No use of the PMN substance involving application methods that generate a vapor, mist, or aerosol; and

2. No release of a manufacturing, processing, or use stream associated with any use of the PMN substance into the waters of the United States exceeding a surface water concentration of 4 ppb.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health and environmental effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific target organ toxicity, neurotoxicity, sensitization, eye damage, skin irritation, and algal toxicity testing would help characterize the potential health and environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.11406.

PMN Number: P–18–404

Chemical Name: Alkylmultiheteroatom, 2-functionalisedalkyl-2-hydroxyalkyl-, polymer with alkylheteroatom-multialkylfunctionalised carbomonocycleheteroatom and multiglycidylether difunctionalised polyalkylene glycol (generic).

CAS Number: Not available.

Basis for action: The PMN states that the use of the PMN substance will be as an epoxy curing agent used in molding formulations for the manufacture of wind turbine blades. Based on estimated physical/chemical properties of the PMN substance and comparison of structurally analogous chemical substances, EPA has identified concerns for pulmonary effects, skin corrosion, eye irritation, skin sensitization, and kidney toxicity if the chemical substance is not used following the limitations noted. The conditions of use

of the PMN substance as described in the PMN include the following protective measures:

1. No manufacturing (including import), processing, or use of the PMN substance that results in inhalation exposures; and

2. No release of a manufacturing, processing, or use stream associated with any use of the PMN substance into the waters of the United States.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that pulmonary toxicity, specific target organ toxicity, and skin sensitization testing using the reconstructed human cornea-like epithelium test method would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11407.

PMN Number: P–19–12

Chemical Name: Benzenedicarboxylic acid, reaction products with isobenzofurandione and diethylene glycol (generic).

CAS Number: Not available.

Basis for action: The PMN states that the use of the PMN substance will be as a resin component for polyisocyanurate resins and specialty polyurethane kits and systems for aerospace and military applications. Based on comparison to structurally analogous chemical substances, EPA has identified concerns for bladder, kidney, and reproductive/developmental toxicity if the chemical substance is not used following the limitation noted. The conditions of use of the PMN substance as described in the PMN include the following protective measure:

- No manufacturing, processing, or use of the substance that results in inhalation exposures.

The proposed SNUR would designate as a ''significant new use'' the absence of this protective measure.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of developmental/reproductive toxicity, specific target organ toxicity, and eye and skin irritation testing would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11408.

PMN Number: P–19–31

Chemical Name: Formaldehyde, polymer with N1-(2-aminoethyl)-alkanediamine, 5-amino-1,3,3-trimethylcyclohexanemethanamine, 2-(chloromethyl)oxirane, 4,4′-(1-methylethylidene)bis[Phenol] and alpha-hydro-omega-hydroxypoly(oxy-1,2-ethanediyl) (generic).

CAS Number: Not available.

Basis for action: The PMN states that the use of the PMN substance will be as a curing agent for epoxy coating systems. Based on the estimated physical/chemical properties of the PMN substance, comparison with structurally analogous chemical substances, and SAR analysis on analogous polycationic polymers, EPA has identified concerns for irritation, lung effects, carcinogenicity, systemic toxicity, neurotoxicity, and aquatic toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No release of a manufacturing, processing, or use stream associated with any use of the PMN substance into the waters of the United States exceeding a surface water concentration of 1 ppb; and

2. No manufacturing, processing, or use of the substance that results in inhalation exposures.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health and environmental effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific target organ toxicity, skin irritation, neurotoxicity, carcinogenicity and aquatic toxicity testing would help characterize the potential health and environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.11409.

PMN Number: P–19–71

Chemical Name: 2,4-Hexadienoic acid, 1,1′-[2-ethyl-2-[(1-oxo-2,4-hexadien-1-yl)oxy]methyl]-1,3-propanediyl] ester.

CAS Number: 2307636–51–5.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as a physical property modifier for polymers. Based on estimated physical/chemical properties, the comparison of structurally analogous chemical substances and SAR analysis on esters, EPA has identified concerns for liver, developmental, and aquatic toxicity if the chemical substance is not used following the limitation noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. Use of the PMN substance only for the confidential use specified in the PMN; and

2. No manufacture of the PMN substance beyond the confidential annual production volume specified in the PMN.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health and environmental effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of reproductive toxicity, specific target organ toxicity, and aquatic toxicity testing would help characterize the potential health and environmental effects of the PMN substance.

CFR Citation: 40 CFR 721.11410.

PMN Number: P–19–72

Chemical Name: 1-Butanol, reaction products with 2-[(2-propen-1-yloxy)methyl]oxirane.

CAS Number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as a raw material used in chemical manufacture. Based on available data on the PMN substance, EPA has identified concerns for acute toxicity, corrosion to all exposed tissues, sensitization, and hematological and skin changes if the chemical substance is not used following the limitation noted. The condition of use of the PMN substance as described in the PMN includes the following protective measure:

- Use of the PMN substance only for the confidential use specified in the PMN;

The proposed SNUR would designate as a ''significant new use'' the absence of this protective measure.

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize

the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of acute toxicity, sensitization, and systemic effects would help characterize the potential health effects of the PMN substance.

CFR Citation: 40 CFR 721.11411.

V. Rationale and Objectives of the Proposed Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these proposed SNURs, EPA concluded that for five chemical substances regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) Orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. As a general matter, EPA believes it is necessary to follow TSCA section 5(e) Orders with a SNUR that identifies the absence of those protective measures as Significant New Uses to ensure that all manufacturers and processors—not just the original submitter—are held to the same standard.

During review of the other 21 chemical substances that are the subject of these SNURs and as further discussed in Unit IV, EPA identified certain circumstances that raised potential risk concerns. EPA determined that deviations from the limitations identified in the submissions could result in changes in the type or form of exposure to the chemical substances and/or increased exposures to the chemical substances and/or changes in the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of the chemical substances, and therefore warranted SNURs. The SNURs would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the certain limitations in the submission.

B. Objectives

EPA is proposing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants:

- To receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.
- To review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- To either determine that the prospective manufacture or processing is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination, before the described significant new use of the chemical substance occurs.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the internet at *http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html.*

VI. Applicability of the Proposed Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this proposed rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. However, TSCA section 5(e) Orders have been issued for five of the 26 chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) Orders from undertaking activities which would be designated as significant new uses. The identities of 21 of the 26 chemical substances subject to this proposed rule have been claimed as confidential (per 40 CFR 720.85) for a chemical substance covered by this action. Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this proposed rule are ongoing.

Therefore, EPA designates November 4, 2019 as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach is to ensure that a person cannot defeat a SNUR by initiating a significant new use before the effective date of the final rule.

Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of that date would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and wait until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

VII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require developing any particular new information (*e.g.,* generating test data) before submission of a SNUN. There is an exception: development of test data is required where the chemical substance subject to the SNUR is also subject to a rule, order or consent agreement under TSCA section 4 (see TSCA section 5(b)(1)).

In the absence of a TSCA section 4 test rule covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. lists potentially useful information identified by EPA that would help characterize the potential health and/or environmental effects of the PMN/SNUN substance for all of the listed SNURs. EPA recognizes that the 2016 Lautenberg Amendments have led to modifications in our approach to testing requirements, including an increased consideration of alternatives to vertebrate testing. Descriptions of tests/information needs are provided for informational purposes only and EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. Pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the potentially useful information. EPA encourages dialogue with Agency representatives to help determine how best the submitter

can meet both the data needs and the objective of TSCA section 4(h). To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.'' The Organisation for Economic Co-operation and Development test guidelines are available from the OECD Bookshop at *http://www.oecdbookshop.org* or SourceOECD at *http://www.sourceoecd.org.*

The potentially useful information listed in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.

VIII. SNUN Submissions

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and 721.25. E–PMN software is available electronically at *http://www.epa.gov/opptintr/newchems.*

IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this proposed rule. EPA's complete economic analysis is available in the docket under docket ID number EPA–HQ–OPPT–2019–0494.

X. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulations and Regulatory Review

This proposed rule would establish SNURs for several new chemical substances that were the subject of PMNs and TSCA section 5(e) Orders. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

According to the PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection activities in this proposed rule have already been approved by OMB pursuant to the PRA under OMB control number 2070–0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Regulatory Support Division, Office of Mission Support (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

Pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of this proposed SNUR would not have a significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a ''significant new use.'' Because these uses are ''new,'' based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was seven in Federal fiscal year (FY) 2013, 13 in FY2014, six in FY2015, 10 in FY2016, 14 in FY2017, and 18 in FY2018 and only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from $16,000 to $2,800. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about $10,116 for qualifying small firms. Therefore, the potential economic impacts of complying with this proposed SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL–5597–1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this action. As such, EPA has determined that this proposed rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 11632: Federalism

This proposed rule would not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This proposed rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175 (65 FR 67249, November 9, 2000), do not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This proposed rule is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This proposed rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this proposed rule is not expected to affect energy supply, distribution, or use and because this proposed rule is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this proposed rule would not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note) does not apply to this action.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This proposed rule does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: October 18, 2019.

Tala Henry,

Deputy Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PARTS 721—[AMENDED]

■ 1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 2. Add §§ 721.11383 through 721.11411 to subpart E to read as follows:

Subpart E—Significant New Uses for Specific Chemical Substances

* * * * *

Secs.

§ 721.11383 Triarylsulfonium salt (generic).
§ 721.11384 Organic acid, compds. with bisphenol A-epichlorohydrin-polypropylene glycol diglycidyl ether polymer-disubstituted amine-disubstituted polypropylene glycol reaction products (generic).
§ 721.11385 Phenol, 4,4′-(1-methylethylidene)bis-, polymer with 2-(chloromethyl)oxirane and alpha-(2-oxiranylmethyl)-omega-(2-oxiranylmethoxy)poly[oxy(methyl-1,2-ethanediyl)], reaction products with disubstituted amine and disubstituted polypropylene glycol, organic acid salts (generic).
§ 721.11386 Organic acid, 2-substituted-, compds. with bisphenol A-epichlorohydrin-polypropylene glycol diglycidyl ether polymer-disubstituted aminedisubstituted polypropylene glycol reaction products (generic).
§ 721.11387 Phenol, 4,4′-(1-methylethylidene)bis-, polymer with alpha-(2-substituted-methylethyl)-omega-(2-substituted-methylethoxy)poly[oxy(methyl-1,2-ethanediyl)], 2-(chloromethyl)oxirane and alpha-(2-oxiranylmethyl)-omega-(2-oxiranylmethoxy)poly[oxy(methyl-1,2-ethanediyl)], alkylphenyl ethers, reaction products with disubstituted amine, organic acid salts (generic).
§ 721.11388 Organic acid, compds. with bisphenol A-epichlorohydrin-disubstituted polypropylene glycol-polypropylene glycol diglycidyl ether polymer alkylphenyl ethers-disubstituted amine reaction products (generic).
§ 721.11389 Organic acid, compds. with bisphenol A-epichlorohydrin-polypropylene glycol diglycidyl ether polymer-disubstituted polypropylene glycol reaction products (generic).
§ 721.11390 Branched cyclic and linear hydrocarbons from plastic depolymerization (generic).
§ 721.11391 Alkane, alkene, styrenic compounds derived from plastic depolymerization (generic).
§ 721.11392 Carbon compound derived from plastic depolymerization (generic).
§ 721.11393 Branched cyclic and linear hydrocarbons from plastic depolymerization (generic).
§ 721.11394 Phosphonic acid, dimethyl ester, polymer with alkyl diols (generic).
§ 721.11395 1H-Imidazole, 1,2,4,5-tetramethyl-.
§ 721.11396 1-Propanaminium, N,N′-(oxydi-2,1-ethanediyl)bis[3-chloro-2-hydroxy-N,N-dimethyl-, chloride (1:2).
§ 721.11397 Fatty acid, polymer with alkanedioic acid dialkyl ester, hydroxyl alkyl substituted alkanediol, substituted carbomonocycle and alkylol substituted alkane (generic).
§ 721.11398 2,5-Furandione, polymer with ethenylbenzene, 4-hydroxy-substituted butyl amide, polymers with epichlorohydrin and trimethylolpropane, sodium salts (generic).
§ 721.11399 2,5-Furandione, polymer with ethenylbenzene, 4-hydroxy-substitutedbutyl [3-[2-[1-[[(substitutedphenyl)amino]carbonyl]-2-oxopropyl]diazenyl]phenyl]methyl amide, polymers with epichlorohydrin and trimethylolpropane, sodium salts (generic).
§ 721.11400 Alkane, bis(alkoxymethyl)-dimethyl- (generic).
§ 721.11401 [Reserved]
§ 721.11402 [Reserved]
§ 721.11403 [Reserved]
§ 721.11404 Butanedioic acid, 2-methylene-, polymer with 2-methyl-2-[(1-oxo-2-propen-1-yl)amino]-1-propanesulfonic acid, sodium zinc salt.
§ 721.11405 Heteromonocycle, alkenoic (1:1) salt, polymer with alpha-(2-methyl-1-oxo-2-propen-1-y)l-omega.-methoxypoly(oxy-1,2-ethanediyl) and methyl-alkenoic acid (generic).
§ 721.11406 Substituted benzylic ether polyethylene glycol alkyl ether derivative (generic).
§ 721.11407 Alkylmultiheteroatom, 2-functionalisedalkyl-2-hydroxyalkyl-, polymer with alkylheteroatom-multialkylfunctionalised carbomonocycleheteroatom and multiglycidylether difunctionalised polyalkylene glycol (generic).
§ 721.11408 Benzenedicarboxylic acid, reaction products with isobenzofurandione and diethylene glycol (generic).
§ 721.11409 Formaldehyde, polymer with N1-(2-aminoethyl)-alkanediamine, 5-amino-1,3,3-trimethylcyclohexanemethanamine, 2-(chloromethyl)oxirane, 4,4′-(1-methylethylidene)bis[Phenol] and alpha-hydro-omega-hydroxypoly(oxy-1,2-ethanediyl) (generic).
§ 721.11410 2,4-Hexadienoic acid, 1,1′-[2-ethyl-2-[(1-oxo-2,4-hexadien-1-yl)oxy]methyl]-1,3-propanediyl] ester.

§ 721.11411 1-Butanol, reaction products with 2-[(2-propen-1-yloxy)methyl]oxirane.

* * * * *

§ 721.11383 Triarylsulfonium salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as triarylsulfonium salt (PMN P–16–548) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to process or use the substance in a manner that generates a vapor, mist, or aerosol.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11384 Organic acid, compds. with bisphenol A-epichlorohydrin-polypropylene glycol diglycidyl ether polymer-disubstituted amine-disubstituted polypropylene glycol reaction products (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as organic acid, compds. with bisphenol A-epichlorohydrin-polypropylene glycol diglycidyl ether polymer-disubstituted amine-disubstituted polypropylene glycol reaction products (PMN P–17–312) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to modify the manufacture, process, or use of the substance that results in the generation of a dust, mist, or aerosol.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 78.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11385 Phenol, 4,4′-(1-methylethylidene)bis-, polymer with 2-(chloromethyl)oxirane and alpha-(2-oxiranylmethyl)-omega-(2-oxiranylmethoxy)poly[oxy(methyl-1,2-ethanediyl)], reaction products with disubstituted amine and disubstituted polypropylene glycol, organic acid salts (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as phenol, 4,4′-(1-methylethylidene)bis-, polymer with 2-(chloromethyl)oxirane and alpha-(2-oxiranylmethyl)-omega-(2-oxiranylmethoxy)poly[oxy(methyl-1,2-ethanediyl)], reaction products with disubstituted amine and disubstituted polypropylene glycol, organic acid salts (PMN P–17–313) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to modify the manufacture, process, or use of the substance that results in the generation of a dust, mist, or aerosol.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 78.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11386 Organic acid, 2-substituted-, compds. with bisphenol A-epichlorohydrin-polypropylene glycol diglycidyl ether polymer-disubstituted aminedisubstituted polypropylene glycol reaction products (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as organic acid, 2-substituted-, compds. with bisphenol A-epichlorohydrin-polypropylene glycol diglycidyl ether polymer-disubstituted aminedisubstituted polypropylene glycol reaction products (PMN P–17–314) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to modify the manufacture, process, or use of the substance that results in the generation of a dust, mist, or aerosol.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 78.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11387 Phenol, 4,4′-(1-methylethylidene)bis-, polymer with alpha-(2-substituted-methylethyl)-omega-(2-substituted-methylethoxy)poly[oxy(methyl-1,2-ethanediyl)], 2-(chloromethyl)oxirane and alpha-(2-oxiranylmethyl)-omega-(2-oxiranylmethoxy)poly[oxy(methyl-1,2-ethanediyl)], alkylphenyl ethers, reaction products with disubstituted amine, organic acid salts (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as phenol, 4,4′-(1-methylethylidene)bis-, polymer with alpha-(2-substituted-methylethyl)-omega-(2-substituted-methylethoxy)poly[oxy(methyl-1,2-ethanediyl)], 2-(chloromethyl)oxirane and alpha-(2-oxiranylmethyl)-omega-(2-oxiranylmethoxy)poly[oxy(methyl-1,2-ethanediyl)], alkylphenyl ethers, reaction products with disubstituted amine, organic acid salts (PMN P–17–315) is subject to reporting under this section for the significant new uses

described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to modify the manufacture, process, or use of the substance that results in the generation of a dust, mist, or aerosol.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 78.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11388 Organic acid, compds. with bisphenol A-epichlorohydrin-disubstituted polypropylene glycol-polypropylene glycol diglycidyl ether polymer alkylphenyl ethers-disubstituted amine reaction products (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as organic acid, compds. with bisphenol A-epichlorohydrin-disubstituted polypropylene glycol-polypropylene glycol diglycidyl ether polymer alkylphenyl ethers-disubstituted amine reaction products (PMN P–17–316) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to modify the manufacture, process, or use of the substance that results in the generation of a dust, mist, or aerosol.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 78.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11389 Organic acid, compds. with bisphenol A-epichlorohydrin-polypropylene glycol diglycidyl ether polymer-disubstituted polypropylene glycol reaction products (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as organic acid, compds. with bisphenol A-epichlorohydrin-polypropylene glycol diglycidyl ether polymer-disubstituted polypropylene glycol reaction products (PMN P–17–317) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to modify the manufacture, process, or use of the substance that results in the generation of a dust, mist, or aerosol.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 78.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11390 Branched cyclic and linear hydrocarbons from plastic depolymerization (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as branched cyclic and linear hydrocarbons from plastic depolymerization (PMN P–17–398) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance that have been refined or blended into other chemical or fuel formulations.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (k)(other than as a refinery feedstock or a fuel blending additive).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11391 Alkane, alkene, styrenic compounds derived from plastic depolymerization (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkane, alkene, styrenic compounds derived from plastic depolymerization (PMN P–17–399) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance that have been refined or blended into other chemical or fuel formulations.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (other than as a refinery feedstock or a fuel blending additive).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11392 Carbon compound derived from plastic depolymerization (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as carbon compound derived from plastic depolymerization (PMN P–18–1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance containing more than 1% of the particles less than 75 microns. It is a significant new use to manufacture the substance other than by the enclosed process described in the premanufacture notice.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part

apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11393 Branched cyclic and linear hydrocarbons from plastic depolymerization (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as branched cyclic and linear hydrocarbons from plastic depolymerization (PMN P–18–28) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance that have been refined or blended into other chemical or fuel formulations.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (other than as a refinery feedstock or a fuel blending additive).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11394 Phosphonic acid, dimethyl ester, polymer with alkyl diols (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as phosphonic acid, dimethyl ester, polymer with alkyl diols (PMN P–18–9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the PMN substance in a manner that generates a dust, mist, or aerosol.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 300.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11395 1H-Imidazole, 1,2,4,5-tetramethyl-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1H-Imidazole, 1,2,4,5-tetramethyl- (PMN P–18–11, CAS No. 1739–83–9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f) and (g).

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 7.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11396 1-Propanaminium, N,N′-(oxydi-2,1-ethanediyl)bis[3-chloro-2-hydroxy-N,N-dimethyl-, chloride (1:2).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1-propanaminium, N,N′-(oxydi-2,1-ethanediyl)bis[3-chloro-2-hydroxy-N,N-dimethyl-, chloride (1:2) (PMN P–18–170, CAS No. 96320–92–2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposures.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 164.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11397 Fatty acid, polymer with alkanedioic acid dialkyl ester, hydroxyl alkyl substituted alkanediol, substituted carbomonocycle and alkylol substituted alkane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fatty acid, polymer with alkanedioic acid dialkyl ester, hydroxyl alkyl substituted alkanediol, substituted carbomonocycle and alkylol substituted alkane (PMN P–18–185) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (o).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11398 2,5-Furandione, polymer with ethenylbenzene, 4-hydroxy-substituted butyl amide, polymers with epichlorohydrin and trimethylolpropane, sodium salts (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as 2,5-furandione, polymer with ethenylbenzene, 4-hydroxy-substituted butyl amide, polymers with epichlorohydrin and trimethylolpropane, sodium salts (PMN P–18–190) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a pigment dispersing aid for pigments in inkjet printing inks.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers and processors of these substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11399 2,5-Furandione, polymer with ethenylbenzene, 4-hydroxy-substitutedbutyl [3-[2-[1-[[(substitutedphenyl)amino]carbonyl]-2-oxopropyl]diazenyl]phenyl]methyl amide, polymers with epichlorohydrin and trimthylolpropane, sodium salts (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as 2,5-furandione, polymer with ethenylbenzene, 4-hydroxy-substitutedbutyl [3-[2-[1-[[(substitutedphenyl)amino]carbonyl]-2-oxopropyl]diazenyl]phenyl]methyl amide, polymers with epichlorohydrin and trimthylolpropane, sodium salts (PMN P–18–191) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a pigment dispersing aid for pigments in inkjet printing inks.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of these substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11400 Alkane, bis(alkoxymethyl)-dimethyl-0 ((generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkane, bis(alkoxymethyl)-dimethyl- (PMN P–18–223) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance greater than the confidential annual production volume specified in the PMN.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11401 [Reserved]

§ 721.11402 [Reserved]

§ 721.11403 [Reserved]

§ 721.11404 Butanedioic acid, 2-methylene-, polymer with 2-methyl-2-[(1-oxo-2-propen-1-yl)amino]-1-propanesulfonic acid, sodium zinc salt.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as butanedioic acid, 2-methylene-, polymer with 2-methyl-2-[(1-oxo-2-propen-1-yl)amino]-1-propanesulfonic acid, sodium zinc salt (PMN P–18–285, CAS No. 2220235–78–7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Releases to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) where N = 143.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11405 Heteromonocycle, alkenoic 1:1 salt, polymer with alpha-(2-methyl-1-oxo-2-propen-1-y)l-omega.-methoxypoly(oxy-1,2-ethanediyl) and methyl-alkenoic acid (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as heteromonocycle, alkenoic 1:1 salt, polymer with alpha-(2-methyl-1-oxo-2-propen-1-y)l-omega.-methoxypoly(oxy-1,2-ethanediyl) and methyl-alkenoic acid (PMN P–18–300) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the PMN substance in a manner that results in particles less than 50 microns. It is a significant new use to use the PMN substance in a manner that results in consumer inhalation or dermal exposure, and use other than as sealed, single-use packets.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11406 Substituted benzylic ether polyethylene glycol alkyl ether derivative (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as substituted benzylic ether polyethylene glycol alkyl ether derivative (PMN P–18–394) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(y)(1).

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 4.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11407 Alkylmultiheteroatom, 2-functionalisedalkyl-2-hydroxyalkyl-, polymer with alkylheteroatom-multialkylfunctionalised carbomonocycleheteroatom and multiglycidylether difunctionalised polyalkylene glycol (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkylmultiheteroatom, 2-functionalisedalkyl-2-hydroxyalkyl-, polymer with alkylheteroatom-multialkylfunctionalised carbomonocycleheteroatom and multiglycidylether difunctionalised polyalkylene glycol (PMN P–18–404) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposures.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11408 Benzenedicarboxylic acid, reaction products with isobenzofurandione and diethylene glycol (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as benzenedicarboxylic acid, reaction products with isobenzofurandione and diethylene glycol (PMN P–19–12) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposures.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11409 Formaldehyde, polymer with N1-(2-aminoethyl)-alkanediamine, 5-amino-1,3,3-trimethylcyclohexanemethanamine, 2-(chloromethyl)oxirane, 4,4′-(1-methylethylidene)bis[Phenol] and alpha-hydro-omega-hydroxypoly(oxy-1,2-ethanediyl) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as formaldehyde, polymer with N1-(2-aminoethyl)-alkanediamine, 5-amino-1,3,3-trimethylcyclohexanemethanamine, 2-(chloromethyl)oxirane, 4,4′-(1-methylethylidene)bis[Phenol] and alpha-hydro-omega-hydroxypoly(oxy-1,2-ethanediyl) (PMN P–19–31) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposures.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 1.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11410 2,4-Hexadienoic acid, 1,1′-[2-ethyl-2-[(1-oxo-2,4-hexadien-1-yl)oxy]methyl]-1,3-propanediyl] ester.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2,4-hexadienoic acid, 1,1′-[2-ethyl-2-[(1-oxo-2,4-hexadien-1-yl)oxy]methyl]-1,3-propanediyl] ester (PMN P–19–71, CAS No. 2307636–51–5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) and (s).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11411 1-Butanol, reaction products with 2-[(2-propen-1-yloxy)methyl]oxirane.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1-butanol, reaction products with 2-[(2-propen-1-yloxy)methyl]oxirane (PMN P–19–72) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i).

[FR Doc. 2019–23388 Filed 11–1–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 190909–0024]

RIN 0648–BI77

Fisheries of the Northeastern United States; Habitat Clam Dredge Exemption Framework

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: NMFS reopens the comment period on the proposed rule to implement the New England Fishery Management Council's Habitat Clam Dredge Exemption Framework Adjustment to its Fishery Management Plans that published on September 17, 2019. The New England Fishery Management Council requested the comment period be reopened due to concerns that an error in a URL in the proposed rule may have prevented some individuals from submitting comments. Reopening the comment period through November 18, 2019, and including the correct URL should ensure all interested parties are able to comment on the proposed action.

DATES: The comment period for the proposed rule published September 17, 2019 (84 FR 48899), is reopened. Public comment must be received by November 18, 2019.

ADDRESSES: You may submit comments, identified by NOAA–NMFS–2019–0043, by either of the following methods:

Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal.

1. Go to *https://www.regulations.gov/document?D=NOAA-NMFS-2019-0043-0001.*

2. Click the ''Comment Now!'' icon, complete the required fields.

3. Enter or attach your comments.

—OR—

Mail: Submit written comments to Michael Pentony, Regional Administrator, National Marine Fisheries Service, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope: ''Comments on the Proposed Rule for Habitat Clam Dredge Exemption Framework.''

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, *etc.*), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

A draft environmental assessment (EA) has been prepared for this action that describes the proposed measures and other considered alternatives, as well as provides an analysis of the impacts of the proposed measures and alternatives. Copies of the specifications document, including the EA and the Initial Regulatory Flexibility Analysis (IRFA), are available on request from Thomas Nies, Executive Director, New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950. These documents are also accessible via the internet at *www.nefmc.org*.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted to the Greater Atlantic Regional Fisheries Office and by email to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–7285.

FOR FURTHER INFORMATION CONTACT: Douglas Potts, Fishery Policy Analyst, 978–281–9341.

SUPPLEMENTARY INFORMATION:

Background

The Great South Channel Habitat Management Area (GSC HMA) was created by the final rule to implement the New England Fishery Management Council's Omnibus Habitat Amendment 2 (OHA2) (83 FR 15240; April 9, 2018). The use of all mobile bottom-tending fishing gear is prohibited in the GSC HMA. The GSC HMA contains complex benthic habitat that is important for juvenile cod and other fish species, and it is susceptible to the adverse impacts of fishing gear. The OHA2 included a 1-year delay of the GSC HMA closure that allowed the surfclam fishery to continue fishing with hydraulic clam dredges in the GSC HMA. This delay was intended to give the Council time to determine if a long-term exemption is warranted. The 1-year delay ended on April 9, 2019, and the GSC HMA is now closed to all mobile bottom-tending fishing gear.

On September 17, 2019, NMFS published in the **Federal Register** a proposed rule to implement the Clam Dredge Exemption Framework with a 30-day comment period that closed on October 17, 2019 (84 FR 48899). Full details of the proposed measures are provided in the proposed rule and are not repeated here. Subsequently, NMFS received a request from the Council to extend the comment period due to concerns that an error in a URL in the proposed rule may have prevented some individuals from submitting comments. NMFS is reopening the comment period on the proposed rule through November 18, 2019, and is including the correct URL to ensure all interested partied have an opportunity to submit comments. Comments submitted during the prior comment period have been incorporated into the public record, and will be fully considered during the preparation of our final determination.

Dated: October 25, 2019.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2019–23768 Filed 11–1–19; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 84, No. 213
Monday, November 4, 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 COMMERCE

Bureau of Economic Analysis

Bureau of Economic Analysis Advisory Committee Meeting

AGENCY: Economics and Statistics Administration, Bureau of Economic Analysis, Department of Commerce.

ACTION: Notice of public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, BEA announces a meeting of the Bureau of Economic Analysis Advisory Committee. The meeting will address proposed improvements, extensions, and research related to BEA's economic accounts. In addition, the meeting will include an update on recent statistical developments.

DATES: Friday, November 15, 2019. The meeting begins at 9:00 a.m. and adjourns at 3:30 p.m.

ADDRESSES: The meeting will take place at the Suitland Federal Center, 4600 Silver Hill Road, Suitland, MD 20746.

FOR FURTHER INFORMATION CONTACT: Gianna Marrone, Program Analyst, U.S. Department of Commerce, Bureau of Economic Analysis, Suitland, MD 20746; phone (301) 278–9282.

Public Participation: This meeting is open to the public. Because of security procedures, anyone planning to attend the meeting must contact Gianna Marrone at BEA (301) 278–9282 or *gianna.marrone@bea.gov.* The meeting is physically accessible to people with disabilities. Requests for foreign language interpretation or other auxiliary aids should be directed to Gianna Marrone at (301) 278–9282 by November 8, 2019.

SUPPLEMENTARY INFORMATION: The Committee was established September 2, 1999. The Committee advises the Director of BEA on matters related to the development and improvement of BEA's national, regional, industry, and international economic accounts, with a focus on new and rapidly growing areas of the U.S. economy. The committee provides recommendations from the perspectives of the economics profession, business, and government.

Dated: October 4, 2019.

Shaunda Villones,

Designated Federal Officer, Bureau of Economic Analysis.

[FR Doc. 2019–23970 Filed 11–1–19; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–220–2019]

Foreign-Trade Zone 28—New Bedford, Massachusetts; Application for Subzone; The Lobster Trap Co.; Bourne, Massachusetts

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the City of New Bedford, grantee of FTZ 28, requesting subzone status for the facility of The Lobster Trap Co., located in Bourne, Massachusetts. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on October 29, 2019.

The proposed subzone (0.32 acres) is located at 290 Shore Road, Bourne. No authorization for production activity has been requested at this time. The proposed subzone would be subject to the existing activation limit of FTZ 28.

In accordance with the Board's regulations, Elizabeth Whiteman of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is December 16, 2019. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to December 30, 2019.

A copy of the application will be available for public inspection in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: October 29, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–24034 Filed 11–1–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–69–2019]

Foreign-Trade Zone 124—Gramercy, Louisiana; Application for Subzone; Frank's International, LLC; New Iberia/Lafayette, Louisiana

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Port of South Louisiana, grantee of FTZ 124, requesting subzone status for the facilities of Frank's International, LLC, located in New Iberia and Lafayette, Louisiana. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on October 29, 2019.

The proposed subzone would consist of the following sites: *Site 1* (117.36 acres) 3500 Segura Road, New Iberia; and, *Site 2* (29.941 acres) 700 East Verot School Road, Block ''E'', Lafayette. A notification of proposed production activity has been submitted and will be published separately for public comment.

In accordance with the FTZ Board's regulations, Camille Evans of the FTZ Staff is designated examiner to review the application and make recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is December 16, 2019. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to December 30, 2019.

A copy of the application will be available for public inspection in the

''Reading Room'' section of the FTZ Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Camille Evans at *Camille.Evans@trade.gov* or (202) 482–2350.

Dated: October 29, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–24035 Filed 11–1–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–68–2019]

Foreign-Trade Zone 12—McAllen, Texas; Application for Production Authority; Black & Decker (U.S.), Inc. (Lithium Ion Battery Assembly for Cordless Power Tools), Mission, Texas

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the McAllen Foreign Trade Zone Inc., grantee of FTZ 12, requesting production authority on behalf of Black & Decker (U.S.), Inc. (Black & Decker), located in Mission, Texas. The application conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.23) was docketed on October 25, 2019.

The Black & Decker facility (180 employees, 17.2 acres) is located within Site 4 of FTZ 12. The facility is used for the manufacture/assembly of cordless power tools and of power tool components (lithium ion batteries, plastic injection molded parts, cordless motors, and certain subassemblies), and for the packaging/kitting of power tools with their components. In 2018, Black & Decker requested production authority in a notification proceeding (15 CFR 400.22 and 400.37). After an initial review, the requested production authority was approved subject to a restriction requiring that lithium ion batteries and related components be admitted in privileged foreign status, which precludes inverted tariff benefits on those inputs (see B–33–2018, 83 FR 50636, October 9, 2018). The pending application proposes to remove that restriction.

If the application were approved, on its domestic sales, Black & Decker would be able to choose the duty rates during customs entry procedures that apply to lithium ion batteries (duty rate: 3.4%) and cordless power tools (duty rate ranges between duty free to 4%) for the foreign-status inputs noted below. The company currently intends to ship a significant portion of its Mission-produced battery packs zone to zone to its manufacturing facility (Subzone 38M) in Fort Mill, South Carolina. Black & Decker would be able to avoid duty on foreign-status components which become scrap/waste. Customs duties also could possibly be deferred or reduced on foreign-status production equipment. The request indicates that the savings from FTZ procedures would help improve the plant's international competitiveness.

Components and materials sourced from abroad (representing 60 percent of the value of the finished battery pack) include lithium ion batteries and related parts (lithium ion cells, assembly housings, cell holders, front insert covers, cover housings, and latches) (duty rate: 3.4%). The request indicates that certain materials/components are subject to special duties under Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

In accordance with the FTZ Board's regulations, Diane Finver of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is January 3, 2020. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to January 21, 2020.

A copy of the application will be available for public inspection in the ''Reading Room'' section of the FTZ Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Diane Finver at *Diane.Finver@trade.gov* or (202) 482–1267.

Dated: October 29, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–24037 Filed 11–1–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Materials and Equipment Technical Advisory Committee; Notice of Open Meeting

The Materials and Equipment Technical Advisory Committee will meet on November 20, 2019, 10:00 a.m., Herbert C. Hoover Building, Room 1894 (Law Library), 14th Street between Constitution & Pennsylvania Avenues NW, Washington, DC The Committee advises the Office of the Assistant Secretary for Export Administration with respect to technical questions that affect the level of export controls applicable to materials and related technology.

Agenda

Open Session

1. Introductions and Opening Remarks by Senior Management.
2. Presentation by Dawn Metters, Sundyne Corp. on ''Industrial Pumps & Compressors.''
3. Presentation by Andrew Souza and Sarah Rodjom, Dept. of State on ''Status of Efforts to List Novichoks and Their Precursors.''
4. Open session report by the regime representatives.

The open session will be accessible via teleconference to 20 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at *Yvette.Springer@bis.doc.gov,* no later than November 13, 2019.

A limited number of seats will be available during the public session of the meeting. Reservations are not accepted. To the extent time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the materials should be forwarded prior to the meeting to Ms. Springer via email.

For more information, call Yvette Springer at (202) 482–2813.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2019–24028 Filed 11–1–19; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–112 and C–570–113]

Certain Collated Steel Staples From the People's Republic of China: Preliminary Affirmative Determinations of Critical Circumstances in the Antidumping and Countervailing Duty Investigations

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that critical circumstances exist with respect to certain imports of certain collated steel staples (collated staples) from the People's Republic of China (China).

DATES: Applicable November 4, 2019.

FOR FURTHER INFORMATION CONTACT: Robert Palmer (CVD) or Sergio Balbontin (AD), 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) 482–9068 or (202) 482–6478, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 6, 2019, Commerce received antidumping (AD) and countervailing duty (CVD) petitions concerning imports of collated staples from China filed in proper form on behalf of Kyocera Senco Industrial Tools, Inc. (the petitioner).[1] On July 3, 2019, Commerce initiated the AD and CVD investigations of collated staples from China.[2]

In the AD investigation, Commerce selected Tianjin Jin Xin Sheng Long Metal Products Co., Ltd. (Tianjin JXSL) and Tianjin Hweshcun Fasteners Manufacturing Co., Ltd. (Tianjin Hweshcun) as mandatory respondents for individual examination.[3] In the CVD investigation, Commerce selected Hai Sheng Xin Group Co., Ltd. (Xin Group), Zhejiang Best Nail Industrial Co., Ltd. (Best Nail),[4] and Ningbo Deli Stationery (Ningbo Deli) as mandatory respondents for individual examination.[5] On September 17, 2019, the petitioner alleged that critical circumstances exist with respect to imports of collated staples from China, pursuant to sections 703(e)(1) and 733(e)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.206.[6] On October 11 and 15, 2019, the petitioner filed a supplement to its critical circumstances allegation for the AD and CVD investigations, respectively.[7]

In accordance with 19 CFR 351.206(c)(2)(i), if the petitioner submits an allegation of critical circumstances more than 20 days before the scheduled date of the preliminary determination, Commerce must issue a preliminary finding whether there is a reasonable basis to believe or suspect that critical circumstances exist by no later than the date of the preliminary determination.[8] In these AD and CVD investigations, the petitioner requested that Commerce issue preliminary critical circumstances determinations on an expedited basis.[9]

Section 703(e)(1) of the Act provides that Commerce, upon receipt of a timely allegation of critical circumstances, will preliminarily determine that critical circumstances exist in CVD investigations if there is a reasonable basis to believe or suspect that: (A) The alleged countervailable subsidy is inconsistent with the Subsidies and Countervailing Measures (SCM) Agreement of the World Trade Organization; and (B) there have been massive imports of the subject merchandise over a relatively short period. Section 733(e)(1) of the Act provides that Commerce, upon receipt of a timely allegation of critical circumstances, will preliminarily determine that critical circumstances exist in AD investigations if there is a reasonable basis to believe or suspect that: (A)(i) There is a history of dumping and material injury by reason of dumped imports in the United States or elsewhere of the subject merchandise, or (ii) the person by whom, or for whose account, the merchandise was imported knew or should have known that the exporter was selling the subject merchandise at less than its fair value and that there was likely to be material injury by reason of such sales; and (B) there have been massive imports of the subject merchandise over a relatively short period.

Sections 351.206(h)(2) and (i) of Commerce's regulations provide that imports must increase by at least 15 percent during the ''relatively short period'' to be considered ''massive'' and defines a ''relatively short period'' as normally being the period beginning on the date the proceeding begins (*i.e.,* the date the petition is filed) and ending at least three months later. Commerce's regulations also provide, however, that if Commerce finds that importers, or exporters or producers, had reason to believe, at some time prior to the beginning of the proceeding, that a proceeding was likely, Commerce may consider a period of not less than three months from that earlier time.[10]

Critical Circumstances Analysis

Alleged Countervailable Subsidies Are Inconsistent With the SCM Agreement

To determine whether an alleged countervailable subsidy is inconsistent with the SCM Agreement, in accordance with section 703(e)(1)(A) of the Act, Commerce considered the evidence currently on the record of the CVD investigation. Specifically, as reflected in the initiation checklist, the following subsidy programs, alleged in the Petition and supported by information reasonably available to the petitioner, appear to be export contingent, which would render them inconsistent with the SCM Agreement: [11]

- Export Loans from Chinese State-Owned Banks
- Export Seller's Credit
- Export Buyer's Credit
- Export Credit Insurance Subsidies
- Export Credit Guarantees

[1] *See* Petitioner's Letter, ''Petitions for the Imposition of Antidumping and Countervailing Duties: Certain Collated Steel Staples from Korea, the People's Republic of China, and Taiwan,'' dated June 6, 2019 (the Petition).

[2] *See Certain Collated Steel Staples from the People's Republic of China: Initiation of Countervailing Duty Investigation,* 84 FR 31840 (July 3, 2019); and *Certain Collated Steel Staples from the People's Republic of China, the Republic of Korea, and Taiwan: Initiation of Less-Than-Fair-Value Investigations,* 84 FR 31833 (July 3, 2019).

[3] *See* Memorandum, ''Less-Than-Fair-Value Investigation of Collated Steel Staples from the People's Republic of China: Respondent Selection,'' dated July 30, 2019.

[4] *See* Memorandum, ''Countervailing Duty Investigation of Certain Collated Steel Staples from the People's Republic of China: Respondent Selection,'' dated July 26, 2019.

[5] *See* Memorandum, ''Countervailing Duty Investigation of Certain Collated Steel Staples from the People's Republic of China: Additional Respondent Selection,'' dated August 19, 2019.

[6] *See* Petitioner's Letter, ''Certain Collated Steel Staples from the People's Republic of China: Allegation of Critical Circumstances,'' dated September 17, 2019 (Critical Circumstances Allegation).

[7] *See* Petitioner's Letter, ''Certain Collated Steel Staples from the People's Republic of China: Supplement to Critical Circumstances Allegation {AD},'' dated October 11, 2019 (Petitioner Supplement to AD Allegation); *see also* Petitioner's Letter, ''Certain Collated Steel Staples from the People's Republic of China: Supplement to Critical Circumstances Allegation {CVD},'' dated October 15, 2019.

[8] The preliminary determination for the AD investigation is currently due no later than November 19, 2019, and the preliminary determination for the CVD investigation is currently due no later than November 4, 2019.

[9] *See* Critical Circumstances Allegation at 2–3.

[10] *See* 19 CFR 351.206(i).

[11] *See* CVD Initiation Checklist: Certain Collated Steel Staples from the People's Republic of China, dated June 26, 2019.

- Subsidies for the Development of Famous Brands and China World Top Brands
- SME International Market Exploration Fund
- Export Assistance Grants
- Export Interest Subsidies for Enterprises Located in Zhejiang Province

Therefore, Commerce preliminarily determines that there is a reasonable basis to believe or suspect that alleged subsidies in the CVD investigation are inconsistent with the SCM Agreement.

History of Dumping and Material Injury/ Knowledge of Sales Below Fair Value and Material Injury

To determine whether there is a history of dumping pursuant to section 733(e)(1)(A)(i) of the Act, Commerce generally considers current or previous AD orders on subject merchandise from the country in question in the United States and current orders imposed by other countries regarding imports of the same merchandise. However, in the Critical Circumstances Allegation, the petitioner did not provide information on the history of dumping.[12]

To determine whether importers knew or should have known that exporters were selling the subject merchandise at less than fair value pursuant to section 733(e)(1)(A)(ii) of the Act, we typically consider the magnitude of dumping margins, including margins alleged in the petition.[13] Commerce has found margins of 15 percent or more (for constructed export price) to 25 percent or more (for export price) to be sufficient for this purpose.[14] The dumping margins of 119.37 percent and 122.55 percent alleged in the AD Petition significantly exceed the 15 to 25 percent threshold.[15] Therefore, on that basis, we preliminarily conclude importers knew, or should have known, that exporters in China were selling at less than fair value (LTFV).

To determine whether importers knew, or should have known, that there was likely to be material injury caused by reason of such imports pursuant section 733(e)(1)(A)(ii) of the Act, Commerce normally will look to the preliminary injury determination of the International Trade Commission (ITC).[16] If the ITC finds a reasonable indication of material injury to the relevant U.S. industry, Commerce will determine that a reasonable basis exists to impute importer knowledge that material injury is likely by reason of such imports. In these investigations, the ITC found that there is a ''reasonable indication'' of material injury to the domestic industry because of the imported subject merchandise.[17] Therefore, the ITC's preliminary injury determination in the AD investigation is sufficient to impute importer knowledge.

Massive Imports

In determining whether there are ''massive imports'' over a ''relatively short period,'' pursuant to sections 703(e)(1)(B) and 733(e)(1)(B) of the Act, Commerce normally compares the import volumes of the subject merchandise for at least three months immediately preceding the filing of the petition (*i.e.,* the base period) to a comparable period of at least three months following the filing of the petition (*i.e.,* the comparison period).[18] Imports will normally be considered massive when imports during the comparison period have increased by 15 percent or more compared to imports during the base period.[19]

Accordingly, to determine preliminarily whether there has been a massive surge in imports for each participating mandatory respondent which provided shipment data, including Tianjin JXSL, Commerce compared the total volume of shipments from June 2019 through August 2019, the comparison period (*i.e.,* all months for which shipment data was available), with the preceding three-month period of March 2019 through May 2019, the base period. Although the petitioner argued that Commerce should use a two-month comparison period for its analysis with respect to Tianjin JXSL,[20] our preference is to use at least a three-month comparison period.[21] There is no such evidence on the record of the AD or CVD proceeding.

Regarding the CVD investigation, for all others, Commerce compared Global Trade Atlas (GTA) data for the period June 2019 through August 2019 with the preceding three-month period of March 2019 through May 2019,[22] after subtracting from the GTA data shipments reported by the mandatory respondents which provided such data. Similarly, regarding the AD investigation, for non-individually examined companies requesting separate rate status, we performed the same comparison. For those respondents in either the CVD or AD investigation that are not participating in the investigation, we preliminarily determine, on the basis of adverse facts available,[23] that there has been a massive surge in imports. Accordingly, based on our analysis of the information on the record, we preliminarily determine that certain producers/ exporters of collated staples from China had massive surges in imports.[24]

Based on the criteria and findings discussed above, we preliminarily determine in the AD investigation that critical circumstances exist with respect to imports of collated staples from China shipped by Tianjin Hweshcun and all other producers and exporters except Tianjin JXSL. Additionally, we preliminarily determine in the CVD investigation that critical circumstances

[12] *See* Critical Circumstances Allegation at 4–5.

[13] *See, e.g., Notice of Preliminary Determinations of Critical Circumstances: Certain Cold-Rolled Carbon Steel Flat Products from Australia, the People's Republic of China, India, the Republic of Korea, the Netherlands, and the Russian Federation,* 67 FR 19157, 19158 (April 18, 2002), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value: Certain Cold-Rolled Carbon Steel Flat Products from Australia,* 67 FR 47509 (July 19, 2002), *Notice of Final Determination of Sales at Less Than Fair Value: Certain Cold-Rolled Carbon Steel Flat Products from the People's Republic of China,* 67 FR 62107 (October 3, 2002), *Notice of Final Determination of Sales at Less Than Fair Value: Certain Cold-Rolled Carbon Steel Flat Products from India,* 67 FR 47518 (July 19, 2002), *Notice of Final Determination of Sales at Less Than Fair Value: Certain Cold-Rolled Carbon Steel Flat Products from Korea,* 67 FR 62124 (October 3, 2002), *Notice of Final Determination of Sales at Less Than Fair Value and Critical Circumstances: Certain Cold-Rolled Carbon Steel Flat Products from The Netherlands,* 67 FR 62112 (October 3, 2002), and *Notice of the Final Determination Sales at Less Than Fair Value and Critical Circumstances: Certain Cold-Rolled Carbon Steel Flat Products from the Russian Federation,* 67 FR 62121 (October 3, 2002).

[14] *Id.*

[15] *See* Petitioner's Letter, ''Certain Collated Steel Staples from China: Petition Supplement,'' dated June 14, 2019, at Exhibit 9.

[16] *See, e.g., Antidumping and Countervailing Duty Investigations of Certain Softwood Lumber Products from Canada: Preliminary Determinations of Critical Circumstances,* 82 FR 19219, 19220 (April 26, 2017) (*Softwood Lumber from Canada Preliminary Critical Circumstances Determination*), unchanged in *Certain Softwood Lumber Products from Canada: Final Affirmative Determination of Sales at Less Than Fair Value and Affirmative Final Determination of Critical Circumstances,* 82 FR 51806, 51807–08 (November 8, 2017) (*Softwood Lumber from Canada Final AD Determination*).

[17] *See Certain Collated Steel Staples from China, Korea, and Taiwan: Investigation Nos. 701–TA–626 and 731–TA–1452–1454 (Preliminary),* 84 FR 35884 (July 25, 2019).

[18] *See Softwood Lumber from Canada Preliminary Critical Circumstances Determination,* 82 FR at 19220, unchanged in *Softwood Lumber from Canada Final AD Determination,* 82 FR at 51807–08.

[19] *Id.*

[20] *See* Petitioner Supplement to AD Allegation at 6–8.

[21] *See* 19 CFR 351.206(h)(2)(i).

[22] Commerce gathered GTA data under the following harmonized tariff schedule number: 8305.20.00.

[23] *See* section 776 of the Act.

[24] *See* Memorandum, ''Certain Collated Steel Staples from the People's Republic of China: Preliminary Massive Imports Analysis,'' dated concurrently with this notice.

exist with respect to imports of collated staples from China shipped by Best Nail, Xin Group, Ningbo Deli, and all other producers and exporters.

Final Critical Circumstances Determinations

We will issue our final determinations concerning critical circumstances when we issue our final CVD and AD determinations. All interested parties will have the opportunity to address these determinations in case briefs to be submitted after the issuance of the preliminary CVD and AD determinations. Commerce will specify the applicable deadlines at a later date.

ITC Notification

In accordance with sections 703(f) and 733(f) of the Act, we will notify the ITC of these preliminary determinations of critical circumstances.

Suspension of Liquidation

In accordance with section 703(e)(2) of the Act, because we have preliminarily found that critical circumstances exist with regard to imports from all producers and exporters of collated staples from China, if we make an affirmative preliminary determination that countervailable subsidies have been provided to these same producers/exporters at above *de minimis* rates, we will instruct U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of subject merchandise from these producers/exporters that are entered, or withdrawn from warehouse for consumption, on or after the date that is 90 days prior to the effective date of provisional measures (*e.g.,* the date of publication in the **Federal Register** of the notice of an affirmative preliminary determination that countervailable subsidies have been provided at above *de minimis* rates). At such time, we will also instruct CBP to require a cash deposit equal to the estimated preliminary subsidy rates reflected in the preliminary determination published in the **Federal Register**. The suspension of liquidation will remain in effect until further notice.

In accordance with section 733(e)(2) of the Act, because we have preliminarily found that critical circumstances exist with regard to imports from certain producers and exporters of collated staples from China, if we make an affirmative preliminary determination that sales at LTFV have been made by these same producers/exporters at above *de minimis* rates, we will instruct CBP to suspend liquidation of all entries of subject merchandise from these producers/exporters that are entered, or withdrawn from warehouse, for consumption on or after the date that is 90 days prior to the effective date of provisional measures (*e.g.,* the date of publication in the **Federal Register** of the notice of an affirmative preliminary determination of sales at LTFV at above *de minimis* rates). At such time, we will also instruct CBP to require a cash deposit equal to the estimated preliminary dumping margins reflected in the preliminary determination published in the **Federal Register**. The suspension of liquidation will remain in effect until further notice.

Notification to Interested Parties

These determinations are issued and published pursuant to section 777(i)(1) of the Act and 19 CFR 351.206(c)(2).

Dated: October 24, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2019–23732 Filed 11–1–19; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–824, A–583–837]

Polyethylene Terephthalate Film, Sheet and Strip From India and Taiwan: Final Results of the Expedited Third Sunset Reviews of the Antidumping Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of these expedited sunset reviews, Commerce finds that revocation of the antidumping duty orders would be likely to lead to the continuation or recurrence of dumping at the levels indicated in the ''Final Results of Review'' section of this notice.

DATES: Applicable November 4, 2019.

FOR FURTHER INFORMATION CONTACT: Jacqueline Arrowsmith AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5255.

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2019, Commerce published the notice of initiation of the third sunset reviews of the antidumping duty orders on polyethylene terephthalate film, sheet, and strip (PET Film) from India and Taiwan [1] pursuant to section 751(c) of the Act.[2] On July 11, 2019, and July 16, 2019, Commerce received notices of intent to participate from the petitioners [3] and Terphane LLC (Terphane), respectively.[4] Each filing was timely submitted within the 15-day deadline specified in 19 CFR 351.218(d)(1)(i). The petitioners and Terphane each claimed interested party status under section 771(9)(C) of the Act as a producer of PET Film in the United States.

On July 31, 2019, Commerce received adequate substantive responses to the notice of initiation from the petitioners as well as from Terphane, a manufacturer of domestic like product, within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[5] On July 31, 2019, Polyplex USA LLC, (Polyplex USA), a domestic interested party, filed a notice of appearance and a substantive response.[6] We received no substantive responses from respondent interested parties with respect to either of the orders covered by these sunset reviews.

On September 3, 2019, Commerce notified the U.S. International Trade

[1] *See Notice of Amended Final: Antidumping Duty Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Polyethylene Terephthalate Film, Sheet, and Strip from India,* 67 FR 44175 (July 1, 2002) (*Antidumping Duty Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 84 FR 31304 (July 1 2019).

[3] The petitioners are DuPont Teijin Films, Mitsubishi Polyester Film, Inc., and SKC, Inc.

[4] *See* Petitioners' Letters, ''Polyethylene Terephthalate (PET) Film, Sheet, and Strip from India: Notice of Intent to Participate in Sunset Review,'' dated July 11; 2019; and ''Polyethylene Terephthalate (PET) Film, Sheet, and Strip from Taiwan: Notice of Intent to Participate in Sunset Review, ''dated July 11, 2019; Terphane's Letter, ''Five-Year (''Sunset'') Review of Antidumping Order on Polyethylene Terephthalate (PET) Film, Sheet, And Strip from India: Notice of Intent to Participate,'' dated July 16, 2019;'' *see also* Terphane's Letter, ''Five-Year (''Sunset'') Review of Antidumping Order on Polyethylene Terephthalate (PET) Film, Sheet, And Strip from Taiwan: Notice of Intent to Participate,'' dated July 16, 2019.

[5] *See* Petitioners' Letters, Polyethylene Terephthalate (PET) Film, Sheet, and Strip from India: Substantive Response to the Notice of Initiation,'' dated July 31, 2019 (Petitioners' India Substantive Response); and, Polyethylene Terephthalate (PET) Film, Sheet, and Strip from Taiwan: Substantive Response to the Notice of Initiation,'' dated July 31, 2019 (Petitioners' Taiwan Substantive Response); *see also*Terphane's Letter, ''Five-Year (''Sunset'') Review of Antidumping Orders on Polyethylene Terephthalate (PET) Film, Sheet, And Strip from India And Taiwan, and Countervailing Duty Order on PET Film, Sheet, And Strip from India: Terphane's Substantive Response, '' dated July 31, 2019 (Terphane's Substantive Response).

[6] *See* Polyplex USA LLC's notice of appearance, dated July 31, 2019; *see also* Polyplex USA LLC's Letter, ''Polyethylene Terephthalate (PET) Film from India and Taiwan: Response to the Notice of Initiation of Five-Year (Sunset) Reviews and Support for Continuation of the Orders,'' dated July 31, 2019.

Commission that it did not receive an adequate substantive response from respondent interested parties.[7] As a result, pursuant to 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce is conducting expedited (120-day) sunset reviews of the antidumping duty orders on PET Film from India and Taiwan.

Scope of the Orders

The products covered by this *Order* is PET Film and is currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under item number 3920.62.00.90. A full description of the scope of the *Order* is contained in the accompanying Issues and Decision Memorandum.[8]

Analysis of Comments Received [9]

All issues raised in these sunset reviews are addressed in the Issues and Decision Memorandum,[10] which is hereby adopted by this notice. The issues discussed in the Issues and Decision Memorandum are the likelihood of continuation or recurrence of dumping and the magnitude of the dumping margin likely to prevail if the orders were revoked. 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 in the Central Records Unit, Room B8024 of the main Commerce building. A list of topics discussed in the Issues and Decision Memorandum is included as an Appendix to this notice. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at *http://enforcement.trade.gov/frn.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Final Results of Reviews

Pursuant to sections 751(c)(1) and 752(c)(1) and (3) of the Act, Commerce determines that revocation of the antidumping duty orders on PET Film from India and Taiwan would be likely to lead to the continuation or recurrence of dumping at weighted-average dumping margins up to 24.10 percent for India and 8.99 percent for Taiwan.

Notification to Interested Parties

This notice also serves as the only reminder to parties subject to 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. Timely notification of the return or destruction of APO materials or conversion to judicial protective orders is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing the final results and this notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: October 29, 2019.

Christian Marsh,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Orders
IV. History of the Orders
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of Dumping
  2. Magnitude of the Dumping Margins Likely to Prevail
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2019–24044 Filed 11–1–19; 8:45 am]

BILLING CODE 3510–DS–P

[7] *See* Commerce's Letter, ''Sunset Reviews Initiated on July 1, 2019,'' dated September 3, 2019.

[8] *See* Memorandum, ''Issues and Decision Memorandum for the Expedited Third Sunset Reviews of the Antidumping Duty Orders on Polyethylene Terephthalate Film, Sheet and Strip from India and Taiwan,'' dated concurrently with this notice (Issues and Decision Memorandum).

[9] 19 CFR 351.218(d)(1)(i) states that where a domestic interested party intends to participate in a sunset review, it must file a notice of intent to participate with Commerce within 15 days after the publications of the notice of initiation. As noted above, Polyplex USA untimely filed its notice of appearance on July 31, 2019. 19 CFR 351.218(d)(1)(iii)(A) states that Commerce will not accept or consider any unsolicited submissions from that party during the course of the review. Accordingly, we have not considered Polyplex USA's submissions.

[10] *See* Issues and Decision Memorandum.

DEPARTMENT OF COMMERCE

International Trade Administration

C–533–825

Polyethylene Terephthalate Film, Sheet, and Strip From India: Final Results of the Expedited Sunset Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this expedited sunset review, the Department of Commerce (Commerce) finds that revocation of the countervailing duty order on polyethylene terephthalate film, sheet, and strip (PET film) from India would be likely to lead to continuation or recurrence of countervailable subsidies as indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable November 4, 2019.

FOR FURTHER INFORMATION CONTACT: Elfi Blum, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0197.

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2019, Commerce published the initiation of the five-year (sunset) review of the countervailing duty order on PET film from India, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[1] Commerce received notices of intent to participate in this sunset review from DuPont Teijin Films, Mitsubishi Polyester Film, Inc., SKC, Inc., and Terphane LLC (collectively, domestic interested parties), within the 15-day period specified in 19 CFR 351.218(d)(1)(i). The domestic interested parties claimed interested party status under section 771(9)(C) of the Act as producers of the domestic like product.

Commerce received adequate substantive responses to the *Notice of Initiation* from the domestic interested parties within the 30-day period specified in 19 CFR 351.218(d)(3)(i). Commerce received no substantive response from any respondent interested parties. In accordance with section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day)

[1] *See Initiation of Five-Year (Sunset) Reviews,* 84 FR 31304 (July 1, 2019).

sunset review of the countervailing duty order on PET film from India.[2]

Scope of the Order

For purposes of the order, the products covered are all gauges of raw, pretreated, or primed polyethylene terephthalate film, sheet and strip, whether extruded or coextruded. Excluded are metallized films and other finished films that have had at least one of their surfaces modified by the application of a performance-enhancing resinous or inorganic layer of more than 0.00001 inches thick. Imports of PET film are classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under item number 3920.62.00.90. HTSUS subheadings are provided for convenience and customs purposes. The written description of the scope of the order is dispositive.

Analysis of Comments Received

All issues raised in this review, including the likelihood of continuation or recurrence of countervailable subsidies and the net countervailable subsidy likely to prevail if the order were revoked, are addressed in the Issues and Decision Memorandum.[3] 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 Services 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 *https://enforcement.trade.gov/frn/index.html.* A list of the issues discussed in the Issues and Decision Memorandum is attached at the appendix to this notice. The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Final Results of Sunset Review

Commerce determines that revocation of the countervailing duty order on PET film from India would be likely to lead to continuation or recurrence of countervailable subsidies at the following rates:

Manufacturers/exporters	Subsidy rates (percent *ad valorem*)
Ester Industries Ltd	20.46
Garware Polyester Ltd	26.70
Polyplex Corporation Ltd	15.82
All Others	22.50

Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a). Timely written notification of the 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

Commerce is issuing and publishing these final results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.221(c)(5)(ii).

Dated: October 29, 2019.

Christian Marsh,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Final Decision Memorandum

I. Summary
II. Background
III. History of the Order
IV. Scope of the Order
V. Discussion of the Issues
1. Likelihood of Continuation or Recurrence of a Countervailable Subsidy
2. Net Countervailable Subsidy Likely to Prevail
3. Nature of the Subsidy
VI. Final Results of Sunset Review
VII. Recommendation

[FR Doc. 2019–24033 Filed 11–1–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–838]

Certain Cold Drawn Mechanical Tubing of Carbon and Alloy Steel From Italy: Partial Rescission of Antidumping Duty Administrative Review; 2017–2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is partially rescinding its administrative review of the antidumping duty order on certain cold drawn mechanical tubing of carbon and alloy steel (cold drawn mechanical tubing) from Italy for the period of review November 22, 2017, through May 31, 2019.

DATES: Applicable November 4, 2019.

FOR FURTHER INFORMATION CONTACT: Robert Scully or Emily Halle, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0572 or (202) 482–0176 respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 3, 2019, Commerce published in the **Federal Register** a notice of ''Opportunity to Request an Administrative Review'' of the antidumping duty (AD) order on cold drawn mechanical tubing from Italy for the period November 22, 2017, through May 31, 2019.[1] On July 29, 2019, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.221(c)(1)(i), Commerce initiated an administrative review of the AD order on cold drawn mechanical tubing from Italy with respect to seven companies.[2] On October 8, 2019, ArcelorMittal Tubular Products LLC, Michigan Seamless Tube, LLC, PTC Alliance Corp., and Webco Industries, Inc.(collectively, the petitioners), timely withdrew their requests for an administrative review of all six companies for which they had requested a review.[3]

Partial Rescission

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested the review withdraws its request within 90 days of the publication date of the notice of initiation of the requested review. The petitioners timely withdrew their review requests for six companies. Because Commerce received no other requests for review of these six

[2] *See Notice of Countervailing Duty Order: Polyethylene Terephthalate Film, Sheet, and Strip from India,* 67 FR 44179 (July 1, 2002) (*Order*).

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited Third Sunset Review of the Countervailing Duty Order on Polyethylene Terephthalate Film, Sheet, and Strip from India,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[1] *See Antidumping or Countervailing Duty Order, Finding or Suspended Investigation; Opportunity to Request Administrative Review,* 84 FR 25521 (June 3, 2019).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 36572 (July 29, 2019).

[3] *See Petitioner's Letter* ''Cold-Drawn Mechanical Tubing from Italy—Domestic Industry's Withdrawal of Request for First Administrative Review.'' Dated October 8, 2019.

companies for which a review was initiated, we are rescinding the review of cold drawn mechanical tubing from Italy for the period November 22, 2017, through May 31, 2019, in part, with respect to these six companies, in accordance with 19 CFR 351.213(d)(1). These six companies are: Alessio Tubi S.p.A, Arvedi Tubi Acciaio S.p.A, Italsempione S.p.A, Marcegaglia Novero S.p.A, Metalfer, S.p.A, and Pipex Italia S.p.A. The review will continue with respect to Dalmine S.p.A.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries. For the companies for which this review is rescinded, antidumping duties shall be assessed at rates equal to the cash deposit rate of estimated antidumping 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 to CBP 15 days after publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as the only reminder to importers whose entries will be liquidated as a result of this rescission notice, of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO 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 terms of an APO is a sanctionable violation.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751 and 777(i)(l) of the Act and 19 CFR 351.213(d)(4).

Dated: October 29, 2019.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–24036 Filed 11–1–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[0648–XR060]

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Notice of availability; extension of public comment period.

SUMMARY: We, NMFS, announce the extension of the comment period for the receipt of 14 (Permit Numbers 23271, 23276, 23278, 23279, 23280, 23284, 23285, 23286, 23287, 23288, 23289, 23290, 23291, 23434) applications for enhancement of survival permits under the Endangered Species Act (ESA) of 1973, as amended (16 U.S.C. 1531 *et seq.*), and proposed entry into an associated Template Safe Harbor Agreement (Agreement) between the applicants and NMFS. The Notice of Receipt for the 14 applications published on October 15, 2019. The proposed enhancement of survival permits and Agreement are intended to promote the survival and recovery of the Southern Oregon/Northern California Coast (SONCC) coho salmon (*Oncorhynchus kisutch*) Evolutionary Significant Unit (ESU), which is listed as threatened under the ESA. We are soliciting review and comment from the public and all interested parties on the applications and associated documents. The close of the comment period is being extended—from November 15, 2019, to December 31, 2019—to provide additional opportunity for public comment.

DATES: Comments or requests for a public hearing on the actions proposed in the applications must be received at the appropriate address or fax number (see **ADDRESSES**) no later than 5 p.m. Pacific standard time on December 31, 2019.

ADDRESSES: Written comments on the applications should be submitted to the California Coastal Office, NMFS, 1655 Heindon Road, Arcata, CA 95521 707–822–7201. Comments may also be submitted via fax to 707–822–4840, or by email to *Shasta.sha@noaa.gov* (include the permit numbers in the subject line of the fax or email).

FOR FURTHER INFORMATION CONTACT: Jim Simondet, Arcata, CA (ph.: 707–822–7201; Fax: 707–825–4840; email: *Shasta.sha@noaa.gov.* Permit application are available upon request through the contact information above, or online at *https://apps.nmfs.noaa.gov* and *https://www.fisheries.noaa.gov/resource/document/shasta-river-template-safe-harbor-agreements-and-site-plans-review.*

SUPPLEMENTARY INFORMATION:

Extension of Comment Period

On October 15, 2019 (84 FR 55145) we (NMFS) published in the **Federal Register** a request for public comment 14 applications for enhancement of survival permits. The public comment period for this action is set to end on November 15, 2019. The comment period is being extended through December 31, 2019, to provide additional opportunity for public comment.

Species Covered in This Notice

The following ESA-listed species is covered in this notice:

- Threatened coho salmon (*Oncorhynchus kisutch*): Southern Oregon/Northern California Coast (SONCC) Evolutionary Significant Unit (ESU).

Authority

Enhancement permits are issued in accordance with Section 10(a)(1)(A) of the ESA (16 U.S.C. 1539(a)(1)(A)) and regulations governing listed fish and wildlife permits (50 CFR part 222, subpart C). NMFS issues permits based on findings that such permits: (1) Are applied for in good faith; (2) if granted and exercised, would not operate to the disadvantage of the listed species that are the subject of the permit; (3) are consistent with the purposes and policies of Section 2 of the ESA; (4) would further a bona fide and necessary or desirable scientific purpose or enhance the propagation or survival of the endangered species, taking into account the benefits anticipated to be derived on behalf of the endangered species; and additional issuance criteria (as listed at 50 CFR 222.308(c)(5–12)). The authority to take listed species is subject to conditions set forth in the permits.

Anyone requesting a hearing on an application listed in this notice should set out the specific reasons why a hearing on that application would be appropriate (see **ADDRESSES**). Such hearings are held at the discretion of the

Assistant Administrator for Fisheries, NMFS.

Permit Applications Received

Fourteen applicants are requesting individual enhancement of survival permits and entry of an associated Agreement that was developed by NMFS, California Department of Fish and Wildlife (CDFW), the Shasta Watershed Conservation Group (SWCG) and the Applicants. The 14 Applicants (Table 1) each developed site plans for their respective properties (*i.e.,* Enrolled Properties) that describe management activities that will be implemented, including beneficial activities for SONCC coho salmon (the covered species). The site plans, Agreement, and enhancement of survival permits are expected to promote the recovery of the covered species on non-federal property within the Shasta River in the Agreement Area (see Figure 1 in the Agreement). The Shasta River is a tributary to the Klamath River and is in Siskiyou County, California. The proposed duration of the Agreement and the associated enhancement of survival permits is 20 years. The proposed enhancement of survival permits would authorize the incidental taking of SONCC coho salmon that may be associated with covered activities, including beneficial management activities, routine ranch management activities, and the potential future return of the enrolled properties to baseline conditions at the end of the Agreement, as defined in the Agreement. The site plans and Agreement specify the beneficial management activities to be carried out on the enrolled properties and a schedule for implementing those activities. The site plan and Agreement are expected to promote the recovery of SONCC coho salmon within the Shasta River within the Agreement Area.

TABLE 1—APPLICANTS AND ASSOCIATED PERMIT NUMBERS FOR THIS NOTICE

Applicant	Permit No.	Enrolled property
Outpost North Annex	23271	Belcampo-North Annex Property, 8030 Siskiyou Blvd., Grenada, CA 96038.
California Department of Fish and Wildlife	23276	Big Springs Ranch Wildlife Area, 41°35′44.76 N 122°27′31.52 W.
Cardoza Ranch	23278	Cardoza Ranch, 3710 East Louie Road, Montague, CA 96064.
Edson Foulke Ditch Company	23279	Edson-Foulke Point of Diversion, 41°43′52.6 N 122°47′46.8 W.
Grenada Irrigation District	23280	Grenada Irrigation District, Point of Diversion 41°38′11.56 N 122°29′22.88 W.
2019 Lowell L. Novy Revocable Trust	23284	Grenada-Novy Ranch, Gazelle—19931 Old Hwy. 99 S, Gazelle, CA 96034, Grenada—2426 County Hwy. A–12, Grenada, CA 96034.
Hidden Valley Ranch	23285	Hidden Valley Ranch, 13521 Big Springs Road, Montague, CA 96064.
Emmerson Investments, Inc	23286	Hole-in-the-Ground Ranch, 11825 Big Springs Road, Montague, CA 96064.
Montague Water Conservation District	23287	Montague Water Conservation District, N 52°,43′ E, approximately 2601 feet from SW corner of Section 25, T43N, R5W, MDB&M, being within the NE¼ of SW¼ of said Section 25.
NB Ranches, Inc	23434	Nicoletti Ranch, 1824 DeSouza Lane, Montague, CA and 2238 DeSouza Lane, Montague, CA.
Outpost Mole Richardson	23288	Parks Creek Ranch, 25801 Old Hwy. 99, Weed, CA 96094.
Rice Livestock Company	23289	Rice Livestock Company, 1730 County Highway A12, Montague, CA.
Emmerson Investments, Inc	23290	Seldom Seen Ranch, 41°54′63.2 N 122°38′35.7 W.
Emmerson Investments, Inc	23291	Shasta Springs Ranch, 21305 Slough Road, Weed, CA 96094.

Under U.S. Fish and Wildlife Service and NMFS' joint Safe Harbor Policy (64 FR 32717, June 17, 1999), Safe Harbor Agreements provide incentives to property owners to restore, enhance, or maintain habitats and/or populations of listed species that result in a net conservation benefit to these species. Under the policy, landowners are provided certainty relative to future property-use restrictions, even if their conservation efforts attract listed species onto enrolled properties or increase the numbers or distribution of listed species already present. Subject to specifications in the relevant documents, these regulatory assurances allow the landowners to alter or modify enrolled property, even if such alteration or modification results in the incidental take of a listed species to such an extent that it returns the species back to the originally agreed upon baseline conditions. NMFS reviewed each present baseline and elevated baseline determination in each site plan. The site plans and Agreement also contain a monitoring component that requires the Applicants to ensure compliance with the terms and conditions, and that the specified baseline levels of habitat for the covered species is maintained on the enrolled property. Results of the monitoring efforts will be provided to NMFS by the Applicants in an annual report for the duration of the 20-year permit term.

Upon approval of the Agreement and site plans, and consistent with the Safe Harbor Policy, NMFS will issue enhancement of survival permits to the Applicants. The enhancement of survival permits will authorize the Applicants to take SONCC coho salmon incidental to the implementation of the covered activities specified in the site plans and Agreement, incidental to other lawful uses of the enrolled property, and to return to present baseline and elevated baseline conditions, if desired, at the end of the site plans and Agreement. In addition to meeting other criteria, actions to be performed under the enhancement of survival permit must not jeopardize the existence of federally listed species.

National Environmental Policy Act

Issuing an ESA section 10(a)(1)(A) permit constitutes a Federal action requiring NMFS to comply with the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) as implemented by 40 CFR parts 1500–1508 and NOAA Administrative Order 216–6, Environmental Review Procedures for Implementing the National Policy Act (1999). NMFS will evaluate the application(s) and determine the level of NEPA analysis needed for this action.

Public Comments Solicited

NMFS invites the public to comment, including any written data, views, or arguments, on the permit applications during the public comment period, which ends on the date specified above. This notice is provided pursuant to Section 10(c) of the ESA (16 U.S.C. 1539(c)), 50 CFR 222.303. All comments and materials received, including names and addresses, will become part of the administrative record and may be released to the public. We provide this

notice in order to allow the public, agencies, or other organizations to review and comment on these documents.

Next Steps

NMFS will evaluate the applications, associated documents, and comments submitted to determine whether the applications meet the requirements of Section 10(a)(1)(A) of the ESA and Federal regulations. The final permit decisions will not be made until after the end of the 30-day public comment period and after NMFS has fully considered all relevant comments received. NMFS will also meet other legal requirements prior to taking final action, including preparation of a biological opinion. NMFS will publish notice of its final action in the **Federal Register**.

Dated: October 29, 2019.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–23964 Filed 11–1–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 181019964–9283–01]

RIN 0648–XG584

Announcement of Hearing and Final Agenda Regarding Proposed Waiver and Regulations Governing the Taking of Marine Mammals

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

ACTION: Notice of hearing; final agenda.

SUMMARY: This notice announces modifications to the final agenda for a hearing before an Administrative Law Judge (ALJ), which was originally published in the **Federal Register** on June 26, 2019.

DATES: NMFS has scheduled a hearing before Administrative Law Judge George J. Jordan to consider the proposed MMPA waiver and the proposed regulations previously published on April 5, 2019 (84 FR 13604). It will begin on Thursday, November 14, 2019 at 1:00 p.m. PDT in the Henry M. Jackson Federal Building, 915 Second Avenue, 4th Floor Auditorium, Seattle, WA 98174.

ADDRESSES: The hearing will be held before Administrative Law Judge George J. Jordan of the United States Coast Guard at the Henry M. Jackson Federal Building, 915 Second Avenue, 4th Floor Auditorium, Seattle, WA 98174.

FOR FURTHER INFORMATION CONTACT: Michael Milstein, NMFS West Coast Region, 1201 NE Lloyd Blvd., Suite 1100, Portland, OR 97232–1274; 503–231–6268.

SUPPLEMENTARY INFORMATION: On February 14, 2005, NMFS received a request from the Makah Indian Tribe for a waiver of the MMPA moratorium on the take of marine mammals to allow for take of ENP gray whales (*Eschrichtius robustus*). The Tribe requested that NMFS authorize a tribal hunt for ENP gray whales in the coastal portion of the Tribe's usual and accustomed fishing area for ceremonial and subsistence purposes and the making and sale of handicrafts. The MMPA imposes a general moratorium on the taking of marine mammals but authorizes the Secretary of Commerce to waive the moratorium and issue regulations governing the take if certain statutory criteria are met.

On April 5, 2019, NMFS published a Notice of Hearing and the associated proposed regulations in the **Federal Register** (84 FR 13639 and 84 FR 13604). Pursuant to an interagency agreement, a Coast Guard Administrative Law Judge was assigned to conduct the formal hearing and issue a recommended decision in this matter under the procedures set forth at 50 CFR part 228.

On June 26, 2019, Judge George J. Jordan issued a notice of final agenda for publication in the **Federal Register** (84 FR 30088). On August 2, 2019, Judge George J. Jordan issued a notice of change to the hearing date and related deadlines for publication in the **Federal Register** (84 FR 37837). Several parties filed motions requesting amendments to the final agenda. After considering these motions and the replies of other parties, Judge Jordan determined certain issues in the Final Agenda should be removed or modified for purposes of clarity and efficiency. These modifications do not present any new issues of fact not previously identified in the Notice of Hearing or the previously published version of the Final Agenda.

Issues To Be Addressed at the Hearing

I. Should a waiver be granted pursuant to 16 U.S.C. 1371(a)(3)(A)?

A. Did NMFS give due regard to the distribution, abundance, breeding habits, and times and lines of migratory movements of the stock subject to the waiver? Will the proposed waiver have a meaningful effect on the distribution, abundance, breeding habits, or migratory movements of the stock subject to the waiver?

1. Distribution and Abundance:

a. What numbers are appropriate to use for ENP, WNP, and PCFG:

i. Carrying capacity.

ii. Current abundance estimates.

iii. Population stability and/or historical fluctuation.

iv. Optimum sustainable population (OSP) levels.

b. What are the maximum number of ENP and PCFG whale deaths and maximum percentage reduction in ENP and PCFG abundance expected to result from Makah hunting over the 10-year waiver period?

i. Would this reduction have any impact on ENP or PCFG abundance?

c. Is the ENP stock currently undergoing an Unusual Mortality Event (UME)? If so, does this merit further consideration before a waiver may be granted?

d. Is the carrying capacity of ENP stock in the summer feeding areas being reduced and does this merit further consideration before a waiver may be granted?

2. Facts pertaining to Breeding Habits:

a. Under the proposed waiver, will hunting or hunt training overlap with the breeding season? Will this most likely occur in December-January?

i. What is the expected frequency of hunt activities during the relevant time period?

ii. Will the boundaries set for the proposed hunt adversely affect mating whales or mothers and calves?

3. Facts pertaining to Time and Lines of Migratory Movements:

a. Does the majority of the ENP stock range from the winter/spring breeding grounds in northern Mexico and southern California to the summer/fall feeding grounds in the Bering, Beaufort, and Chukchi seas? Should the Okhotsk Sea be included in the migratory range?

b. Does the ENP stock migrate between the breeding and feeding grounds between December and May?

i. Is the timing of the southbound migration being altered due to a longer feeding season in the Arctic?

c. Will migrating ENP whales generally be encountered only during even-year hunts?

i. How long is it expected to take for a migrating ENP whale to pass through the proposed hunt boundary?

ii. Proportionally, how much of the migratory range is included in the proposed hunt boundary?

iii. What is the expected range and duration of hunting activities during the even-year hunts?

iv. How many whales are likely to be subjected to hunt or training activities?

d. Does the PCFG spend the summer and fall feeding season off the Pacific coast of North America from northern California to northern Vancouver Island? Are some PCFG whales also present in the feeding area throughout the winter?

i. Are PCFG whales expected to be encountered during both even-and odd-year hunts?

ii. Is the PCFG further delineated into sub-groups with distinct feeding areas? Do PCFG whales randomly choose feeding areas or are they internally or externally recruited into sub-groups?

iii. Will the proposed waiver have a disproportionate impact on PCFG whales in the Makah Tribe's Usual and Accustomed (U&A) hunting area? Particularly, will it have an impact on reproductive females?

e. Will non-lethal hunting activities result in a lasting effect on ENP/PCFG migratory movements?

B. Are NMFS's Determinations Consistent with the MMPA's Purposes and Policies?

1. Facts pertaining to the Health and Stability of the Marine Ecosystem and Functioning of Marine Mammals within their Ecosystems:

a. Is the northern California Current ecosystem the appropriate ecosystem to focus on for this proceeding? Should the focus instead be on a smaller biologically relevant scale such as the northern Washington coastal environment or an even more localized area such as the Makah U&A?

b. What effect would the waiver have on the relevant ecosystem(s) or area(s)?

i. What role do gray whales play in structuring the relevant ecosystem? Does this differ in the various geographical areas in which gray whales are present?

ii. In light of NMFS's assertion that ''most effects of the hunt would be temporary and localized,'' does the environmental role and impact of the small groups of whales feeding in the Makah U&A necessitate separate consideration under the MMPA?

iii. Would the level of hunting proposed affect only a small fraction of the ENP stock and the stock's ecosystems? Should the effects on ENP stock as a whole be compared and contrasted to the effects on the PCFG subset?

c. How do non-lethal activities such as training approaches and training harpoon throws affect whale health and behavior?

d. Consideration of waiver's collateral effects on WNP stock.

i. Do WNP whales occasionally migrate along with ENP whales to the North American breeding grounds, or are these whales in fact a Western Feeding Group (WFG) of the ENP stock?

ii. If WNP whales are present in the ENP migration, how many are expected? Is this number constant or does it fluctuate?

iii. What is the appropriate calculation for the likelihood that a WNP whale will be approached, struck, or killed?

iv. Should struck or lost whales that cannot be identified as ENP stock be considered to be WNP whales rather than PCFG whales?

2. Facts pertaining to Stocks to Attaining or Maintaining Optimum Sustainable Population (OSP) Levels:

a. Is NMFS's conclusion that ENP stock are within OSP levels, at 85 percent carrying capacity, and with an 88 percent likelihood that the stock is above its maximum net productivity level scientifically valid?

i. Does this account for the possibility of an Unusual Mortality Event as discussed in section I.A.1.c., above?

ii. Will the removal of whales pursuant to this waiver affect these calculations?

b. What are the effects on the OSP of WNP whales if a WNP whale is killed?

II. Do NMFS's proposed regulations satisfy the regulatory requirements in 16 U.S.C. 1373?

A. Did NMFS Consider all Enumerated Factors in Prescribing Regulations?

1. Facts pertaining to the effect of regulations on existing and future levels of marine mammal species and population stocks (16 U.S.C. 1373(b)(1)):

a. Many issues related to this factor are discussed in Section I, pertaining to the Requirements for Waiver.

b. Are the protections in the waiver, such as reduced strike and landing limits, new strike limits for PCFG whales and PCFG females, minimum abundance threshold for PCFG whales, photographic and genetic matching, restrictions on additional strikes, restriction of the hunt to U&A waters, 10-year sunset provision sufficiently protective?

c. Are the protections for WNP whales sufficient and appropriate, including alternating hunt seasons, a limit of three strikes during even-year hunts, a ban on hunting during November and June, seasonal restriction on training harpoon throws in odd-numbered years, restriction on multiple strikes within 24 hours in even-year hunts, and the requirement that if a WNP is confirmed to be struck, the hunt will cease until steps are taken to ensure such an event will not recur?

2. Facts pertaining to existing international treaty and agreement obligations of the United States (16 U.S.C. 1373(b)(2)):

a. The United States is a signatory to the International Convention for the Regulation of Whaling (ICRW). The ICRW establishes the International Whaling Commission (IWC), which sets catch limits for aboriginal subsistence whaling.

i. Since 1997, the IWC has routinely approved an aboriginal subsistence catch limit for ENP gray whales for joint use by the United States and the Russian Federation.

ii. The United States and the Russian Federation have been routinely, and are currently, parties to a bilateral agreement that allocates the IWC catch limit between the two countries and allows either country to transfer to the other any unused allocation.

iii. The IWC gray whale catch limit is currently 140 per year, with 5 gray whales per year allocated to the United States

iv. If the waiver at issue here is not approved, will the United States continue to transfer the unused portion of the gray whale catch limit to the Russian Federation for use by Chukotkan natives, as has been current practice?

v. Does the proposed hunt comply with the IWC conservation objectives for WNP, ENP, and PCFG whales?

vi. Is the proposed hunt an aboriginal subsistence hunt as defined by the IWC?

3. Facts pertaining to the marine ecosystem and related environmental considerations (16 U.S.C. 1373(b)(3)):

a. Is NMFS's risk analysis sufficiently conservative and based on the best available scientific evidence?

b. Is consideration of cumulative impacts, including those from military exercises, marine energy and coastal development, and climate change, necessary under the MMPA? If so, is there evidence these factors were considered?

c. Were all local impacts that must be considered under the MMPA adequately considered?

4. Facts pertaining to the conservation, development, and utilization of fishery resources (16 U.S.C. 1373(b)(4)):

a. NMFS asserts the proposed hunt will have no effect on the conservation, development, and utilization of fishery resources.

5. Facts pertaining to the economic and technological feasibility of implementation (16 U.S.C. 1373(b)(5)):

a. What are the specific costs to NMFS and to the Makah Tribe associated with

regulating a hunt under the proposed regulations? Are these feasible?

b. What are the specific technological requirements associated with managing and carrying out a hunt? Are these feasible?

c. What are the costs of enforcing the various restrictions contained in the regulations? Are these feasible?

d. Who is specifically tasked with each type of enforcement (*i.e.* training restrictions, strike restrictions, use and sale restrictions on edible and non-edible whale parts) and do those persons/organizations have the necessary training and authority to carry out their obligations?

e. How will records be kept and shared amongst the necessary parties? How will any discrepancies in the records be resolved?

f. Is the use of photo-identification technology economically and technologically feasible? How quickly can identification be made? Is genetic identification more scientifically reliable and how does its economic and technological feasibility compare?

6. Other factors not enumerated in 16 U.S.C. 1373(b), but raised by parties to this proceeding and meriting consideration:

a. What is the appropriate degree to which the analysis in *Anderson* v. *Evans,* 371 F.3d 475 (9th Cir. 2011) should be considered in this proceeding?

b. Are the definitions contained in the proposed regulations adequate or do they contain ambiguities, omissions, and/or inconsistencies?

B. Restrictions in the Proposed Regulations.

1. Issues pertaining to the proposed restrictions on the number of animals that may be taken in any calendar year (16 U.S.C. 1373(c)(1)):

a. Hunt permits may authorize no more than three gray whales to be landed in an even-year hunt and no more than one to be landed in an odd-year hunt. No more than three strikes are permitted during an even-year hunt and no more than two are permitted in an odd-year hunt.

b. Additional restrictions are placed on the taking of PCFG whales and WNP whales.

c. How were the low-abundance triggers for PCFG whales, which would cause hunting activity to cease, determined?

2. Issues pertaining to the proposed restrictions on the age, size, sex, or any combination thereof of animals that may be taken (16 U.S.C. 1373(c)(2)):

a. Are the limits set on authorized strikes of PCFG females appropriate?

b. Are there, or should there be, limitations on approaches or strikes on calves or mother-and-calf pairs?

3. Issues pertaining to the season or other period of time within which animals may be taken (16 U.S.C. 1373(c)(3)):

a. The hunting seasons are split into ''even-year hunts,'' during which hunting would be authorized from December 1 of an odd-numbered year until May 31 of the following even-numbered year, and ''odd-year hunts,'' during which hunting would be authorized from July 1 through October 31 of the odd-numbered year.

4. Issues pertaining to the manner and locations in which animals may be taken (16 U.S.C. 1373(c)(4)):

a. The proposed waiver and regulations authorize training exercises, including approaches and training harpoon throws. A question has been raised as to whether the inclusion of training exercises is necessary and/or appropriate.

b. Do the definitions of ''land'' and ''landing'' provide sufficient information about where the Makah Tribe would be permitted to land whales? Are consultations with other Federal and state agencies necessary (see 16 U.S.C. 1382)?

c. Are the definitions of ''strike'' and ''struck'' ambiguous? Specifically, issues have been raised regarding the single-strike limit within 24 hours (whether a harpoon strike followed by a firearm shot consist of a single ''strike'' or two separate strikes, and whether this will lead to unnecessary suffering on the part of a whale that is struck but not immediately killed); whether whales can be appropriately identified as belonging to WNP stock, ENP stock, or the PCFG during a 24-hour post-strike period; whether the use of crossbows or other devices to obtain genetic material from a struck whale should also be considered a strike; and whether the struck-and-lost limits proposed are inconsistent with the definition of ''strike.''

d. Will independent observers be present at every hunt or only certain hunts? How are these observers selected and trained?

e. Should the potential for an off-shore hunt to result in the taking of more migratory ENP whales and fewer PCFG/Makah U&A whales be considered?

5. Issues pertaining to techniques which have been found to cause undue fatalities to any species of marine mammal (16 U.S.C. 1373(c)(5)):

a. None identified.

6. Issues related to other proposed restrictions not specifically enumerated in 16 U.S.C. 1373(c):

a. Restrictions on the use or sale of gray whale products:

i. Do the restrictions on utilization of edible products of ENP gray whales off-reservation unfairly burden enrolled Makah Tribe members living elsewhere? Are such members permitted to share ENP gray whale products with members of their immediate households who are not enrolled in the Makah Tribe?

ii. Are there any restrictions on the resale of handicrafts by persons who are not enrolled members of the Makah tribe, either on a small or large scale?

iii. Are there restrictions on the international sale or transportation of handicrafts?

III. Other Issues for Consideration

A. What is the relevance in this proceeding of the Treaty of Neah Bay, between the Makah Tribe and the United States, which explicitly protects the tribe's right to hunt whales?

1. Is the entire constellation of activities involved in hunting whales integral to the Makah Tribe?

2. How central is whaling to Makah Tribal identity? Does the Tribe have a continuing traditional dependence?

3. Does the Makah Tribe have a nutritional, subsistence, and cultural need for whaling?

4. Is any traditional dependence on whaling obviated by the Makah Tribe's engagement in sealing starting in the latter half of the 19th century and the near-cessation of whale hunting after 1927?

5. Is it possible for the Makah Tribe to substitute other, non-lethal activities and maintain their traditional ties to whaling?

The presiding officer, Judge George J. Jordan, prepared the contents of this notice. A copy of the draft notice Judge Jordan submitted to the NMFS Regulations Unit for filing with the Office of the Federal Register (OFR) was made available to all parties to this proceeding. The NMFS Regulations Unit reviewed the notice to ensure consistency with the OFR filing requirements. NMFS was otherwise not involved in the review of the contents of the notice. The signature of NMFS West Coast Regional Administrator Barry Thom is required to authorize the filing of the notice with the OFR.

Dated: October 30, 2019.

Barry A. Thom,

Regional Administrator, West Coast Region, National Marine Fisheries Service.

[FR Doc. 2019–24042 Filed 11–1–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2019–ICCD–0105]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Federal Direct Loan Program Regulations for Forbearance and Loan Rehabilitation

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before December 4, 2019.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2019–ICCD–0105. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208, D, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Federal Direct Loan Program Regulations for Forbearance and Loan Rehabilitation.

OMB Control Number: 1845–0119.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 129,027.

Total Estimated Number of Annual Burden Hours: 35,094.

Abstract: This information collection for the Direct Loan (DL) Program is related to regulations for dealing with defaulted loans and forbearance in § 685.205 and reasonable and affordable loan rehabilitation in § 685.211. We are requesting an extension of the current burden calculated for this information collection. These regulations provide additional flexibilities for Direct Loan borrowers and permit oral requests for forbearance, as well as allow a borrower to object to the initially established reasonable and affordable loan repayment amount. In addition, if a borrower incurs changes to his or her financial circumstances, the borrower can provide supporting documentation to change the amount of the reasonable and affordable loan monthly repayment amount. There has been no change to the regulatory language.

Dated: October 30, 2019.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer.

[FR Doc. 2019–24059 Filed 11–1–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2019–ICCD–0104]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Federal Perkins Loan Program Regulations and General Provisions Regulations

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before December 4, 2019.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2019–ICCD–0104. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208, D, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize

the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Federal Perkins Loan Program Regulations and General Provisions Regulations.

OMB Control Number: 1845–0019.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Private Sector; Individuals or Households; State, Local, and Tribal Governments.*Total Estimated Number of Annual Responses:* 11,616,710.

Total Estimated Number of Annual Burden Hours: 6,247,152.

Abstract: This request is for continued approval of the reporting and record-keeping requirements that are contained in the General Provisions regulations as well as the specific program regulations for the Federal Perkins Loan program, the Federal Work-Study program, and the Federal Supplemental Educational Opportunities Grant program. This purpose of this submission is to extend this collection for the next three year period. The information collection requirements are necessary to determine eligibility to receive program benefits and to prevent fraud and abuse of program funds.

Dated: October 30, 2019.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer.

[FR Doc. 2019–24009 Filed 11–1–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2019–ICCD–0139]

Agency Information Collection Activities; Comment Request; Federal Student Aid User Experience Design Research Generic Clearance

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before January 3, 2020.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2019–ICCD–0139. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave, SW, LBJ, Room 6W208, D, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Federal Student Aid User Experience Design Research Generic Clearance.

OMB Control Number: 1845–New.

Type of Review: A new information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 262,400.

Total Estimated Number of Annual Burden Hours: 74,975.

Abstract: Federal Student Aid (FSA) seeks to obtain OMB approval of a Fast Track Process (5-day) generic clearance to collect qualitative feedback for the Next Generation Financial Services Environment (Next Gen). FSA will collect, analyze, and interpret information gathered through this generic clearance to identify strengths and weaknesses of current service delivery and make improvements based on feedback. The solicitation of feedback will target areas such as: Consistency, personalization, intuitiveness, accessibility, ease of use, proactive communication, and efficiency. The collection of this information will allow FSA to deliver clear, consistent information and readily accessible self-service options at every stage of the student aid lifecycle. The insights collected from our customers and stakeholders will help ensure that users have a consistent, efficient, and satisfying experience with FSA's programs.

Dated: October 30, 2019.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer.

[FR Doc. 2019–24027 Filed 11–1–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[Case Number 2019–005; EERE–2019–BT–WAV–0010]

Energy Conservation Program: Decision and Order Granting a Waiver to Anker Innovations Limited From the Department of Energy External Power Supplies Test Procedure

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of Decision and Order.

SUMMARY: The U.S. Department of Energy (''DOE'') gives notice of a Decision and Order (Case Number 2019–005) that grants to Anker Innovations Limited (''Anker'') a waiver from specified portions of the DOE test procedure for determining the energy efficiency of a specified external power supply basic model. Under the Decision and Order, Anker is required to test and rate the specified basic model in accordance with the alternate test procedure specified in the Decision and Order.

DATES: The Decision and Order is effective on November 4, 2019. The Decision and Order will terminate upon the compliance date of any future amendment to the test procedure for external power supplies located at 10 CFR part 430, subpart B, appendix Z that addresses the issues presented in this waiver. At such time, Anker must use the relevant test procedure for this external power supply for any testing to demonstrate compliance with the applicable standards, and any other representations of energy use.

FOR FURTHER INFORMATION CONTACT:

Ms. Lucy deButts, 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. Email: *AS_Waiver_Requests@ee.doe.gov.*

Mr. Michael Kido, U.S. Department of Energy, Office of the General Counsel, Mail Stop GC–33, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585–0103. Telephone: (202) 586–8145. Email: *Michael.Kido@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: In accordance with Title 10 of the Code of Federal Regulations (10 CFR 430.27(f)(2)), DOE gives notice of the issuance of its Decision and Order as set forth below. The Decision and Order grants Anker a waiver from the applicable test procedure at 10 CFR part 430, subpart B, appendix Z for the specified basic model of external power supply, and provides that Anker must test and rate such external power supply using the alternate test procedure specified in the Decision and Order. Anker's representations concerning the energy efficiency of the specified basic model must be based on testing according to the provisions and restrictions in the alternate test procedure set forth in the Decision and Order, and the representations must fairly disclose the test results. Distributors, retailers, and private labelers are held to the same requirements when making representations regarding the energy efficiency of this product. (42 U.S.C. 6293(c))

Manufacturers not currently distributing in commerce in the United States external power supplies employing a technology or characteristic that results in the same need for a waiver from the applicable test procedure must petition for, and be granted a waiver prior to, the distribution in commerce of such products in the United States. Manufacturers may also submit a request for interim waiver pursuant to the requirements of 10 CFR 430.27.

Signed in Washington, DC, on October 23, 2019.

Alexander N. Fitzsimmons,

Acting Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

Case #2019–005

Decision and Order

I. Background and Authority

The Energy Policy and Conservation Act, as amended (''EPCA''),[1] authorizes the U.S. Department of Energy (''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 [2] 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 for certain types of consumer products. These products include external power supplies (''EPSs''), the focus of this document. (42 U.S.C. 6291(36); 42 U.S.C. 6295(u))

The energy conservation program under EPCA consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA include definitions (42 U.S.C. 6291), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), energy conservation standards (42 U.S.C. 6295), 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 that product (42 U.S.C. 6293(c)). Similarly, DOE must use these test procedures to determine whether the product complies with relevant standards promulgated under EPCA. (42 U.S.C. 6295(s))

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE is required to follow when prescribing or amending test procedures for covered products. EPCA requires that any test procedures prescribed or amended under this section must be reasonably designed to produce test results that reflect the energy efficiency, energy use or estimated annual operating cost of a covered product during a representative average use cycle or period of use and requires that test procedures not be unduly burdensome to conduct. (42 U.S.C.6293(b)(3)) The test procedure for external power supplies is contained in the Code of Federal Regulations (''CFR'') at 10 CFR part 430, subpart B, Appendix Z, *Uniform Test Method for Measuring the Energy Consumption of External Power Supplies* (''Appendix Z'').

Any interested person may submit a petition for waiver from DOE's test procedure requirements. 10 CFR 430.27(a)(1). DOE will grant a waiver from the test procedure requirements if DOE determines either that the basic model for which the waiver was requested contains a design characteristic that prevents testing of the basic model according to the prescribed test procedures, or that the prescribed test procedures evaluate the basic model in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 430.27(f)(2). DOE may grant the waiver subject to conditions, including adherence to alternate test procedures. *Id.*

II. Anker's Petition for Waiver: Assertions and Determinations

By letter dated April 12, 2019, Anker filed a petition for waiver and a petition

[1] 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).

[2] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated as Part A.

for interim waiver from the DOE test procedure applicable to EPSs set forth in Appendix Z.[3] Anker stated that the specified basic model includes adaptive ports that meet the provisions of the International Electrotechnical Commission's ''Universal serial bus interfaces for data and power—Part 1–2: Common components—USB Power Delivery'' (''IEC 62680–1–2:2017'') specification. The IEC 62680–1–2:2017 specification describes the particular architecture, protocols, power supply behavior, connectors, and cabling necessary for managing power delivery over a universal serial bus (''USB'') connection at power levels of up to 100 watts (''W''). The purpose behind this specification is to help provide a standardized approach for power supply and peripheral developers to ensure backward compatibility while retaining product design and marketing flexibility. See generally, IEC 62680–1–2:2017 (Abstract) (describing the standard's general provisions and purpose).

Anker stated that the adaptive ports on the basic model identified in its petition meet the IEC 62680–1–2:2017 specification. Anker asserted that testing the adaptive ports that meet the IEC 62680–1–2:2017 specification at 15 watts at the lowest nameplate output voltage (*i.e.,* 5 volts, 3 amps) does not reflect actual energy use in the field, and that, at this voltage level, these ports do not exceed 10 watts for almost all usage conditions. Accordingly, the petitioner argued that the current DOE test procedure results in a measurement that is grossly unrepresentative of the actual energy consumption characteristics of the EPS in the real world.

Under the current DOE test procedure, average active-mode efficiency for an adaptive EPS is measured by testing the units twice—once at the highest achievable output voltage (''V'') and once at the lowest achievable output voltage. The test procedure requires that active-mode efficiency be measured at four loading conditions relative to the nameplate output current of the EPS. See 10 CFR 430.23(bb) and Appendix Z. The lowest achievable output voltage supported by the USB Power Delivery Specification is 5V and the specified nameplate current at this voltage output is 3 amps (''A''), resulting in a power output of 15W. Anker contends that while the IEC 62680–1–2:2017 specification requires the tested EPS to support this power output, the 15W at 5V condition will be rarely used and only for brief periods of time, and that adaptive EPSs operating at 5V do not exceed 10W for almost all usage conditions.

Anker requested use of an alternate test procedure to test and rate a specific EPS basic model. The basic model at issue features two USB–A non-adaptive ports, and two USB–C adaptive ports. In its suggested alternate test procedure, Anker suggested that testing be required only at the highest nameplate output voltage by loading both USB–A output ports at a combined power draw of 10 watts (''W'') (*i.e.,* 5 volts, 1 amp per USB–A port) for the 100% loading condition, and both USB–C output ports at a combined power draw of 90W (*i.e.,* 20 volts, 2.25 amps per USB–C port) for the 100% loading condition. The 75%, 50%, and 25% loading conditions would then be scaled accordingly (*i.e.,* 0.75 amps, 0.5 amps 0.25 amps for each USB–A port at 5 volts, respectively; and 1.688 amps, 1.125 amps, 0.563 amps for each USB–C output port at 20 volts, respectively.)

On July 17, 2019, DOE published a notice that announced its receipt of the petition for waiver and granted Anker an interim waiver. 84 FR 34167 (''Notice of Petition for Waiver''). In the Notice of Petition for Waiver, DOE reviewed the adaptive external power supply model listed in the waiver and initially agreed with the petitioner's claim that the test procedure at Appendix Z would test the model in a manner that is unrepresentative of its energy use. DOE also reviewed the alternate procedure suggested by the petitioner and initially found that it would also evaluate the basic model in a manner unrepresentative of its true energy characteristics because it effectively would test the EPS only at the highest nameplate output voltage. As discussed, it is the testing of the lowest achievable output voltage that is not representative of the energy use of ports that meet the IEC 62680–1–2:2017 specification and which must necessarily serve as the focus of any relevant alternate test procedure when evaluating the energy use of an EPS device meeting this specification.

In the Interim Waiver Order, DOE required use of an alternate test procedure consistent with previous test procedure waivers for similarly situated basic models.[4] Under the alternate test procedure specified in the Interim Waiver Order, the adaptive ports that meet the IEC 62680–1–2:2017 specification must be tested at an output power of 10W at the lowest nameplate output voltage, 5 volts, instead of 15W. The loading conditions at 75%, 50%, and 25% must be scaled accordingly (*i.e.,* 7.5W, 5W, 2.5W, respectively). For the highest nameplate output voltage, the specified EPS basic model must be tested according to the current EPS test procedure provisions for multiple-voltage EPSs as prescribed in section 4(b) of Appendix Z.

In addition, the Notice of Petition for Waiver also solicited comments from interested parties on all aspects of the petition and the alternate test procedure specified as part of DOE's Interim Waiver Order. *Id.* DOE received no comments in response to that document.

For the reasons explained here and in the earlier Notice of Petition for Waiver, absent a waiver the basic model identified by Anker in its petition cannot be tested and rated for energy consumption on a basis representative of its true energy consumption characteristics. DOE has reviewed the test procedure suggested by Anker and concludes that it also would not allow for the accurate measurement of the energy use of the specified external power supply. Instead, DOE has determined that the alternate test procedure required under the Interim Waiver Order allows for the accurate measurement of the energy use of the specified external power supply basic model, while alleviating the testing problems associated with Anker's implementation of DOE's applicable EPS test procedure for the specified basic model.

Thus, DOE is requiring that Anker test and rate the external power supply EPS basic model for which it has requested a waiver according to the alternate test procedure specified in the Decision and Order, which is identical to the procedure provided in the interim waiver.

This Decision and Order applies only to the basic model listed and does not extend to any other basic models. DOE evaluates and grants waivers for only those basic models specifically set out in the petition, not future models that may be manufactured by the petitioner. Anker may request that DOE extend the scope of this waiver to include additional basic models that employ the same technology as those listed in this

[3] The specific basic model for which the petition applies is EPS basic model A2041. This basic model name was provided by Anker in its April 12, 2019 petition, which is available at: *http://www.regulations.gov/docket?D=EERE-2019-BT-WAV-0010.*

[4] See Notice of Decision and Order Granting Individual Waivers to Apple Inc., Microsoft Corporation, Poin2 Lab and Hefei Bitland Information Technology Co., From the Department of Energy External Power Supplies Test Procedure. 83 FR 11738 (March 16, 2018). See also, Notice of Decision and Order Granting Waiver to Huawei Technologies, Co. Ltd. 83 FR 25448 (June 1, 2018).

waiver. 10 CFR 430.27(g). Anker may also submit another petition for waiver from the test procedure for additional basic models that employ a different technology and meet the criteria for test procedure waivers. 10 CFR 430.27(a)(1).

DOE notes that it may modify or rescind the waiver at any time upon DOE's determination that the factual basis underlying the petition for waiver is incorrect, or upon a determination that the results from the alternate test procedure are unrepresentative of the basic model's true energy consumption characteristics. 10 CFR 430.27(k)(1). Likewise, Anker may request that DOE rescind or modify the waiver if the company discovers an error in the information provided to DOE as part of its petition, determines that the waiver is no longer needed, or for other appropriate reasons. 10 CFR 430.27(k)(2).

III. Consultations With Other Agencies

In accordance with 10 CFR 430.27(f)(2), DOE consulted with the Federal Trade Commission (''FTC'') staff concerning the Anker petition for waiver. The FTC staff did not have any objections to DOE granting a waiver to Anker for the specified basic model.

IV. Order

After careful consideration of all the material that was submitted by Anker in this matter, it is *ordered* that:

(1) Anker must, as of the date of publication of this Order in the **Federal Register**, test and rate the Anker-branded basic model A2041 adaptive external power supply with the alternate test procedure as set forth in paragraph (2):

(2) The alternate test procedure for the Anker basic model referenced in paragraph (1) of this Order is the test procedure for external power supplies prescribed by DOE at 10 CFR part 430, subpart B, appendix Z, except that under section 4(a)(i)(E) and Table 1 of Appendix Z, when testing at the lowest achievable output voltage, ports that meet the IEC 62680–1–2:2017 specification must be tested such that the 100% nameplate loading condition shall be 2 amps (which corresponds to an output power of 10 watts). The 75%, 50%, and 25% loading conditions shall be scaled accordingly and the nameplate output power of such ports, at the lowest output voltage, shall be equal to 10 watts. All other requirements of Appendix Z and DOE's regulations remain applicable.

(3) *Representations.* Anker may not make representations about the energy efficiency of the basic model listed in paragraph (1) of this Order for compliance, marketing, or other purposes unless the basic model has been tested in accordance with the provisions set forth in paragraph (2) and such representations fairly disclose the results of such testing.

(4) This waiver shall remain in effect according to the provisions of 10 CFR 430.27.

(5) This waiver is issued on the condition that the statements, representations, and documents provided by Anker are valid. If Anker makes any modifications to the controls or configurations of the basic model, the waiver will no longer be valid and Anker will either be required to use the current Federal test method or submit a new application for a test procedure waiver. DOE may rescind or modify this waiver at any time if it determines the factual basis underlying the petition for waiver is incorrect, or the results from the alternate test procedure are unrepresentative of a basic model's true energy consumption characteristics. 10 CFR 430.27(k)(1). Likewise, Anker may request that DOE rescind or modify the waiver if Anker discovers an error in the information provided to DOE as part of its petition, determines that the waiver is no longer needed, or for other appropriate reasons. 10 CFR 430.27(k)(2).

(6) Granting of this waiver does not release Anker from the certification requirements set forth at 10 CFR part 429.

Signed in Washington, DC, on October 23, 2019.

Alexander N. Fitzsimmons,

Acting Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2019–24046 Filed 11–1–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Extension of a Currently Approved Information Collection for the State Energy Program

AGENCY: Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy.

ACTION: Notice and request for comments.

SUMMARY: The Department of Energy (DOE), pursuant to the Paperwork Reduction Act of 1995, intends to extend for three years a currently approved collection of information with the Office of Management and Budget (OMB). The information collection request, State Energy Program, was previously approved on June 30, 2017 under OMB Control No. 1910–5126 and its current expiration date is June 30, 2020.

DATES: Comments regarding this collection must be received on or before January 3, 2020. If you anticipate difficulty in submitting comments within that period, contact the person listed below as soon as possible.

ADDRESSES: Written comments may be sent to Gregory Davoren, EE–5W, U.S. Department of Energy, 1000 Independence Ave. SW, Washington, DC 20585 or by email at *Gregory.Davoren@ee.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Amy Royden-Bloom, EE–5W, U.S. Department of Energy, 1000 Independence Ave. SW, Washington, DC 20585 or by email at *Amy.Royden-Bloom@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the extended collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. This information collection request contains: (1) *OMB No.:* 1910–5126; (2) *Information Collection Request Title:* ''State Energy Program (SEP)''; (3) *Type of Review:* Extension of a Currently Approved Collection; (4) *Purpose:* To collect information on the status of grantee activities, expenditures, and results, to ensure that program funds are being used appropriately, effectively and expeditiously; (5) *Annual Estimated Number of Respondents:* 56; (6) *Annual Estimated Number of Total Responses:* 224; (7) *Annual Estimated Number of Burden Hours:* 7,456; (8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $315,232.

Statutory Authority: Title 42, Chapter 81, Subchapter III, Part A of the United States Code (U.S.C.), (42 U.S.C. 6867(a)).

Issued in Washington, DC, October 22, 2019.

AnnaMaria Garcia,

Director, Weatherization and Intergovernmental Program Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy.

[FR Doc. 2019–24041 Filed 11–1–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 8046–004]

Big Wood Canal Company; Notice of Amendment of Application for an Amendment of Conduit Exemption Accepted for Filing and Soliciting Comments, Motions To Intervene, Protests, Recommendations, and Terms and Conditions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Amendment of Application for Amendment of Conduit Exemption.

b. *Project No.:* 8046–004.

c. *Date Filed:* October 24, 2019.

d. *Applicant:* Big Wood Canal Company.

e. *Name of Project:* Sagebrush Hydroelectric Project.

f. *Location:* The project is located on the South Gooding Main Canal in Lincoln County, near Gooding, Idaho. The project occupies federal lands administered by the U.S. Bureau of Land Management.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Mr. Nicholas E. Josten, GeoSense LLC, 2742 Saint Charles Ave., Idaho Falls, ID 83404, (208) 528–6152.

i. *FERC Contact:* Linda Stewart, (202) 502–8184, *linda.stewart@ferc.gov*.

j. *Deadline for filing responsive documents:* Due to the small size of the proposed project, as well as the resource agency consultation letters filed with the application, the 60-day timeframe specified in 18 CFR 4.34(b) for filing all comments, motions to intervene, protests, recommendations, terms and conditions, and prescriptions is shortened to 30 days from the issuance date of this notice. All reply comments must be filed with the Commission within 45 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–8046–004.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, it must also serve a copy of the document on that resource agency.

k. *Description of Request:* On September 25, 2019 the Secretary of the Commission issued a Notice of Application for Amendment of Conduit Exemption for the Sagebrush Project. The notice described Big Wood Canal Company's (exemptee) request to amend the conduit exemption, filed on August 22, 2019, and supplemented on September 20, 2019. On October 24, 2019, the exemptee filed additional information to reflect a proposed design change to its amendment application. Instead of removing the existing powerhouse, which contains three turbine generating units with a total installed capacity of 315 kilowatts (kW), and constructing a new powerhouse containing a single 475-kW turbine generating unit immediately downstream of the existing intake system, the exemptee now proposes to partially remove the existing powerhouse and to construct a new powerhouse adjacent to the downstream wall of the existing powerhouse. The new powerhouse would contain a single 475-kW turbine generating unit, as originally proposed by the exemptee. Additionally, instead of removing the approximately 400-foot-long existing, buried penstocks (three pipes) and excavating an open tailrace channel along the route of the existing penstocks, the exemptee now proposes to replace the existing penstocks with a single penstock.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE, Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's website at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number, P–8046, in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, and .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified deadline date for the particular application.

n. Any entity who intervened in the amendment proceeding (sub docket P–8046–004) pursuant to the September 25, 2019 Notice of Application for Amendment of Conduit Exemption need not intervene again.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', ''MOTION TO INTERVENE,'' ''REPLY COMMENTS,'' ''RECOMMENDATIONS,'' ''TERMS AND CONDITIONS,'' or ''PRESCRIPTIONS;'' (2) set forth in the heading, the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). A copy of all other filings in reference to this application must be accompanied by

proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: October 28, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–23985 Filed 11–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. Cp20–5–000]

Notice of Request Under Blanket Authorization; Southern Star Central Gas Pipeline, Inc.

Take notice that on October 17, 2019, Southern Star Central Gas Pipeline, Inc. (Southern Star), 4700 Highway 56, Owensboro, Kentucky 42301, filed a prior notice application pursuant to sections 157.205, and 157.216(b) of the Federal Energy Regulatory Commission's (Commission) regulations under the Natural Gas Act (NGA), and Southern Star's blanket certificate issued in Docket No. CP82–479–000. Southern Star requests authorization to abandon two wells, and approximately 855 feet of 4.5-inch diameter lateral pipeline in Southern Star's South Welda Storage Field in Anderson County, Kansas, all as more fully set forth in the application, which is open to the public for inspection. The filing may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY, (202) 502–8659.

Specifically, Southern Star proposes to abandon one well, SW #70, which is an injection/withdrawal, another well, SWB #21, which is a recovery well, approximately 855 feet of 4.5-inch diameter lateral pipeline, all located in Anderson County, Kansas.

Any questions regarding this application should be directed to Cindy Thompson Manager, Regulatory, Southern Star Central Gas Pipeline, Inc., 4700 Highway 56, Owensboro, Kentucky 42301 or phone (270) 852–4655, or by email at *cindy.thompson@southernstar.com*

Any person or the Commission's staff may, within 60 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the regulations under the NGA (18 CFR 157.205), a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the allowed time for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, and will be notified of any meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenter will not receive copies of all documents filed by other parties or issued by the Commission and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 3 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

Dated: October 28, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–23983 Filed 11–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12796–010]

City of Wadsworth, Ohio; Notice of Application for Surrender of License, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Proceeding:* Application for surrender of license.

b. *Project No.:* 12796–010.

c. *Date Filed:* October 21, 2019.

d. *Licensee:* City of Wadsworth, OH.

e. *Name of Project:* Robert C Byrd Project.

f. *Location:* The project is located on the U.S. Army Corps of Engineers RC Byrd Locks and Dam on the Ohio River in Gallia County, Ohio, and Mason County, West Virginia.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Licensee Contact:* Mr. Robert Patrick, The City of Wadsworth, OH, 120 Maple Street, Wadsworth, OH, (330) 335–2777, *rpatrick@wadsworthcity.org*

i. *FERC Contact:* Ms. Rebecca Martin, (202) 502–6012, *Rebecca.martin@ferc.gov*

j. Deadline for filing comments, interventions, and protests is November 18, 2019. The Commission strongly encourages electronic filing. Please file motions to intervene, protests and comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–12796–010.

k. *Description of Project Facilities:* The unconstructed project would include: (1) A 1,200-foot-long intake channel conveying flow to two equally sized intakes approximately 60 feet wide by 73 feet high; (2) a trash rack located in front of each of the generating unit intakes, with a bar spacing of approximately 8 inches; (3) a reinforced concrete powerhouse measuring approximately 258 feet long by 145 feet wide by 110 feet high, and housing two bulb-type turbine generator units with a total installed capacity of 50 megawatt; (4) a 900-foot-long tailrace channel; (5) a 2.41-mile-long, 138-kilovolt transmission line, and (6) appurtenant facilities. The transmission line would cross the Ohio River from the proposed power plant in Mason County, West Virginia to a point of connection at an existing American Electric Power substation near Apple Grove, West Virginia.

l. *Description of Request:* The licensee proposes to surrender the license because it has determined that the project is no longer financially advantageous. No construction has occurred at the project since the license was issued on August 30, 2017. The project area would remain in its pre-licensed, pre-construction condition. No ground disturbing activities would occur as a result of this surrender.

m. This filing may be viewed on the Commission's website at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction in the Commission's Public Reference Room located at 888 First Street NE, Room 2A, Washington, DC 20426, or by calling (202) 502–8371.

n. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

o. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .212 and .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

p. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to the surrender application that is the subject of this notice. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

q. Agency Comments—Federal, state, and local agencies are invited to file comments on the described proceeding. If any agency does not file comments within the time specified for filing comments, it will be presumed to have no comments.

Dated: October 28, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–23987 Filed 11–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP20–3–000]

Columbia Gas of Maryland, Inc.; Notice of Application

Take notice that on October 11, 2019, Columbia Gas of Maryland, Inc. (CMD), 121 Champion Way, Suite 100, Canonsburg, Pennsylvania 15317, filed in Docket No. CP20–3–000 an application pursuant to section 7(f) of the Natural Gas Act (NGA) requesting a service area determination so that it may expand or enlarge its facilities without further Commission authorization at a small location on the Pennsylvania/Maryland border, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions concerning this application may be directed to Meagan Moore, Senior Counsel, or Kenneth W. Christman, Assistant General Counsel, Columbia Gas of Maryland, Inc., 121 Champion Way, Suite 100, Canonsburg, Pennsylvania 15317 by telephone at (724) 416–6347 (Moore) or (724) 416–6315 (Christman); or by email at *mbmoore@nisource.com* (Moore) or *kchrist@nisource.com* (Christman).

CMD is a local gas distribution company providing natural gas service to customers in northwestern Maryland that is regulated by the Maryland Public Service Commission. Specifically, CMD plans to acquire a regulator set at the Mt. Savage Point of Delivery (POD), located in Somerset County, Pennsylvania, and associated downstream distribution pipeline, which CMD currently accepts gas supplies from at the Pennsylvania/Maryland border. CMD is seeking a service area determination to operate the approximately 60 feet of pipeline in Pennsylvania from the Mt. Savage POD to a point along the Maryland border where the existing piping downstream of the POD connects with CMD's distribution piping in Allegany County, Maryland. CMD states it does not now or in the future intend to serve

customers in Pennsylvania. CMD also requests that the Commission determine that CMD qualifies as a local distribution company for the purposes of transportation under section 311 of the Natural Gas Policy Act of 1978 and that it be granted waiver of all reporting and accounting requirements, as well as other rules and regulations that are normally applicable to natural gas companies subject to the Commission's jurisdiction.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 3 copies of filings made in the proceeding with the Commission and must provide a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list and will be notified of any meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission and will not have the right to seek court review of the Commission's final order.

As of the February 27, 2018 date of the Commission's order in Docket No. CP16–4–001, the Commission will apply its revised practice concerning out-of-time motions to intervene in any new Natural Gas Act section 3 or section 7 proceeding.[1] Persons desiring to become a party to a certificate proceeding are to intervene in a timely manner. If seeking to intervene out-of-time, the movant is required to ''show good cause why the time limitation should be waived,'' and should provide justification by reference to factors set forth in Rule 214(d)(1) of the Commission's Rules and Regulations.[2]

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 3 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

Comment Date: 5:00 p.m. Eastern Time on November 18, 2019.

Dated: October 28, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–23981 Filed 11–1–19; 8:45 am]

BILLING CODE 6717–01–P

[1] *Tennessee Gas Pipeline Company, L.L.C.,* 162 FERC ¶ 61,167 at ¶ 50 (2018).

[2] 18 CFR 385.214(d)(1).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 6398–024]

Hackett Mills Hydro Associates; Notice of Intent To File License Application, Filing of Pre-Application Document, Approving Use of the Traditional Licensing Process

a. *Type of Filing:* Notice of Intent to File License Application and Request to Use the Traditional Licensing Process.

b. *Project No.:* 6398–024.

c. *Date Filed:* August 29, 2019.

d. *Submitted By:* Hackett Mills Hydro Associates.

e. *Name of Project:* Hackett Mills Project.

f. *Location:* On the Little Androscoggin River in the towns of Poland and Minot, in Androscoggin County, Maine.

g. *Filed Pursuant to:* 18 CFR 5.3 of the Commission's regulations.

h. *Potential Applicant Contact:* Michael Scarzello, Eagle Creek Renewable Energy, 116 N State Street, P.O. Box 167, Neshkoro, WI 54960–0167; (973) 998–8400; email—*Michael.Scarzello@eaglecreekre.com.*

i. *FERC Contact:* Karen Sughrue at (202) 502–8556; or email at *karen.sughrue@ferc.gov.*

j. Hackett Mills Hydro Associates filed its request to use the Traditional Licensing Process on August 29, 2019. Hackett Mills Hydro Associates provided public notice of its request on August 28, 2019. In a letter dated October 28, 2019, the Director of the Division of Hydropower Licensing approved Hackett Mills Hydro Associates' request to use the Traditional Licensing Process.

k. With this notice, we are initiating informal consultation with the U.S. Fish and Wildlife Service and/or NOAA Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR, Part 402; and NOAA Fisheries under section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act and implementing regulations at 50 CFR 600.920. We are also initiating consultation with the Maine State Historic Preservation Officer, as required by section 106, National Historic Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating Hackett Mills Hydro Associates as the Commission's non-federal representative for carrying out informal

consultation pursuant to section 7 of the Endangered Species Act and section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act; and consultation pursuant to section 106 of the National Historic Preservation Act.

m. Hackett Mills Hydro Associates filed a Pre-Application Document (PAD; including a proposed process plan and schedule) with the Commission, pursuant to 18 CFR 5.6 of the Commission's regulations.

n. A copy of the PAD is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website (*http://www.ferc.gov*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). A copy is also available for inspection and reproduction at the address in paragraph h.

o. Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filing and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Dated: October 28, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–23982 Filed 11–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP19–500–000]

Northern Natural Gas Company; Notice of Schedule for Environmental Review of the Palmyra to South Sioux City A-Line Abandonment Project

On August 15, 2019, Northern Natural Gas Company (Northern) filed an application in Docket No. CP19–500–000 requesting a Certificate of Public Convenience and Necessity pursuant to Sections 7(b) and Section 7(c) of the Natural Gas Act to abandon, construct, and operate certain natural gas pipeline facilities. The proposed project is known as the Palmyra to South Sioux City A-Line Abandonment Project (Project) and would ensure safe and efficient operation of Northern's existing pipeline system.

On August 29, 2019, the Federal Energy Regulatory Commission (Commission or FERC) issued its Notice of Application for the Project. Among other things, that notice alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's Environmental Assessment (EA) for the Project. This instant notice identifies the FERC staff's planned schedule for the completion of the EA for the Project.

Schedule for Environmental Review

Issuance of EA—December 13, 2019
90-day Federal Authorization Decision Deadline—March 12, 2020

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Project Description

The Project involves the abandonment in place of a total of approximately 118 miles of 20-inch-diameter and 16-inch-diameter pipeline on its A-Line pipeline system in Otoe, Lancaster, Saunders, Dodge, Burt, Thurston, and Dakota Counties, Nebraska. In addition, Northern would construct and operate approximately 4.2 miles of 24-inch-diameter pipeline loop [1] and associated appurtenances in Otoe and Dodge Counties, Nebraska. Northern states that after Commission approval of the Project, the abandoned pipeline would be purchased and removed by a third-party salvage company.

Background

On September 18, 2019, the Commission issued a *Notice of Intent to Prepare an Environmental Assessment for the Proposed Palmyra to South Sioux City A-Line Abandonment Project and Request for Comments on Environmental Issues* (NOI). The NOI was sent to affected landowners; federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. In response to the NOI, the Commission received comments from the Rosebud Sioux Tribe, the Nebraska Department of Natural Resources, the Lower Platte South Natural Resources District, and one landowner. The primary issues raised by the commentors are cultural resources; surface waters and wetlands; land use; and floodplains. All substantive comments will be addressed in the EA.

[1] A loop is a pipeline that is constructed adjacent to another pipeline for the purpose of increasing capacity in this portion of the system.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of all formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Additional information about the Project is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC website (*www.ferc.gov*). Using the ''eLibrary'' link, select ''General Search'' from the eLibrary menu, enter the selected date range and ''Docket Number'' excluding the last three digits (*i.e.,* CP19–500), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov.* The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: October 28, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–23986 Filed 11–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC19–34–000]

Commission Information Collection Activities (FERC–725J); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is submitting its information collection FERC–725J (Definition of the Bulk Electric System) to the Office of Management and Budget (OMB) for review of the information collection requirements. Any interested person may file comments directly with OMB and should address a copy of

those comments to the Commission as explained below. The Commission previously published a Notice in the **Federal Register** (84 FR 40038, August 13, 2019) requesting public comments. The Commission received no comments and is making this notation in its submittal to OMB.

DATES: Comments on the collection of information are due by December 4, 2019.

ADDRESSES: Comments filed with OMB, identified by the OMB Control No. 1902–0259, should be sent via email to the Office of Information and Regulatory Affairs: *oira_submission@omb.gov,* Attention: Federal Energy Regulatory Commission Desk Officer.

A copy of the comments should also be sent to the Commission, in Docket No. IC19–34–000, by either of the following methods:

- *eFiling at Commission's Website: http://www.ferc.gov/docs-filing/efiling.asp.*
- *Mail/Hand Delivery/Courier:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* by telephone at (202) 502–8663, and by fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Title: FERC–725J (Definition of the Bulk Electric System).

OMB Control No.: 1902–0259.

Type of Request: Three-year extension of the FERC–725J with no changes to the current reporting requirements.

Abstract: On December 20, 2012, the Commission issued Order No. 773, a Final Rule approving the North American Electric Reliability Corporation's (NERC) modification to the definition of ''bulk electric system'' and the Rules of Procedure exception process, effective July 1, 2013. On April 18, 2013, in Order No. 773–A, the Commission largely affirmed its findings in Order No. 773. In Order Nos. 773 and 773–A, the Commission directed NERC to modify the definition of bulk electric system in two respects: (1) Modify the local network exclusion (exclusion E3) to remove the 100 kV minimum operating voltage to allow systems that include one or more looped configurations connected below 100 kV to be eligible for the local network exclusion; and (2) modify the exclusions to ensure that generator interconnection facilities at or above 100 kV connected to bulk electric system generators identified in inclusion I2 are not excluded from the bulk electric system.[1]

Type of Respondents: Generator owners, distribution providers, other NERC-registered entities.

Estimate of Annual Burden:[2] The Commission estimates the annual public reporting burden and cost[3] for the information collection as follows.

FERC–725J (DEFINITION OF THE BULK ELECTRIC SYSTEM)

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden (hrs.) and cost ($) per response	Total annual burden hours & total annual cost ($)	Cost per responsent ($)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Generator Owners, Distribution Providers, and Transmission Owners (Exception Request).	20	1	20	94 hrs.; $7,708 ..	1,880 hrs.; $154,160.	$7,708
All Registered Entities (Implementation Plans and Compliance).	186	1	186	350 hrs.; $28,700	65,100 hrs.; $5,338,200.	28,700
Local Distribution Determinations ...	1	1	1	92 hrs.; $7,544 ..	92 hrs.; $7,544 ..	7,544
Total	.....	.....	207	.....	67,072 hrs.; $5,499,904.	

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

[1] *Revisions to Electric Reliability Organization Definition of Bulk Electric System and Rules of Procedure,* Order No. 773, 141 FERC ¶ 61,236 (2012); *order on reh'g,* Order No. 773–A, 143 FERC ¶ 61,053 (2013); *order on reh'g and clarification,* 144 FERC ¶ 61,174 (2013); *aff'd sub nom., People of the State of New York and the Pub. Serv. Comm'n of New York* v. *FERC,* No. 13–2316 (2d. Cir. 2015). On June 13, 2013, the Commission granted NERC's request for extension of time and extended the effective date for the revised definition of bulk electric system and the Rules of Procedure exception process to July 1, 2014. *Revisions to Electric Reliability Organization Definition of Bulk Electric System and Rules of Procedure,* 143 FERC ¶ 61,231, at P 13 (2013). On March 20, 2014, the Commission approved NERC's revisions to the definition of bulk electric system and determined the revisions either adequately address the Commission's Order Nos. 773 and 773–A directives or provide an equally effective and efficient approach. See *order approving revised definition,* 146 FERC ¶ 61,199 (2014).

[2] Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. See 5 CFR 1320 for additional information on the definition of information collection burden.

[3] The estimated hourly cost (salary plus benefits) is based on the figures for May 2018 posted by the Bureau of Labor Statistics for the Utilities sector (available at *http://www.bls.gov/oes/current/naics2_22.htm*) and updated March 2019 for benefits information (at *http://www.bls.gov/news.release/ecec.nr0.htm*). The hourly estimates for salary plus benefits are:

—Legal (code 23–0000), $142.86.

—File Clerks (code 43–4071), $34.50.

—Electrical Engineer (code 17–2071), $68.17.

The average hourly burden cost for this collection is $81.84 [($142.86 + $34.50 + $68.17)/3 = $81.84] and is rounded to $82.00 an hour.

Dated: October 28, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–23984 Filed 11–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC20–2–000]

Commission Information Collection Activities (FERC–577); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved requirements and burden in information collection, FERC–577 (Natural Gas Facilities: Environmental Review and Compliance).

DATES: Comments on the collection of information are due January 3, 2020.

ADDRESSES: You may submit comments (identified by Docket No. IC20–2–000) by either of the following methods:

- *eFiling at Commission's Website: http://www.ferc.gov/docs-filing/efiling.asp.*
- Mail: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663, and fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Title: FERC–577, Natural Gas Facilities: Environmental Review and Compliance.

OMB Control No.: 1902–0128.

Type of Request: Three-year extension of the FERC–577 with no changes to the current reporting requirements.

Abstract: The FERC–577 contains the Commission's information collection pertaining to regulations which implement the National Environmental Policy Act (NEPA) as well as the reporting requirements for landowner notifications. These requirements are contained in 18 CFR parts 2, 157, 284, and 380. The information to be submitted includes draft environmental material in accordance with the provisions of Part 380 of FERC's regulations in order to implement the Commission's procedures under NEPA. Without such information, the Commission would be unable to fulfill its statutory responsibilities under the Natural Gas Act (NGA), NEPA, and the Energy Policy Act of 2005. Specifically, these responsibilities include ensuring company activities remain consistent with the public interest, which is specified in the NGA and inherent in the other statutes.

Type of Respondents: Companies proposing Natural Gas Projects under section 7 and Jurisdictional Gas Pipeline and Storage Companies.

Estimate of Annual Burden.[1] The Commission estimates the annual public reporting burden and cost [2] for the information collection as follows.

FERC–577, NATURAL GAS FACILITIES: ENVIRONMENTAL REVIEW AND COMPLIANCE

	Number of respondents	Number of responses per respondent	Total number of responses	Average burden hours & average cost per response ($) (rounded)	Total annual burden hours & total annual cost ($) (rounded)	Cost per respondent ($) (rounded)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1) = (6)
Gas Pipeline Certificates [3]	101	16	1,616	193.518 hours; $15,481.	312,725 hours; $25,018,007.	$247,703
Landowners Notification [4]	164	144	23,616	2 hours; $160	47,232 hours; $3,778,560.	23,040
Total			25,232		359,957 hours; $28,796,567.	

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: October 28, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–23980 Filed 11–1–19; 8:45 am]

BILLING CODE 6717–01–P

[1] Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. See 5 CFR 1320 for additional information on the definition of information collection burden.

[2] The Commission staff estimates that industry is similarly situated in terms of hourly cost (for wages plus benefits). Based on the Commission's FY (Fiscal Year) 2019 average cost (for wages plus benefits), $80.00/hour is used.

[3] Requirements are found in 18 CFR Parts 2, 157, and 380.

[4] Requirements are found in 18 CFR 157(d), 157(f), 2.55(a), 2.55(b), 284.11, and 380.15.

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2016–0027; FRL–10001–72–OAR]

Agency Information Collection Activities: Information Collection Request (ICR) for On-Highway Motorcycle Certification and Compliance Program; EPA ICR Number 2535.02, OMB Control Number 2060–0710

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an Information Collection Request (ICR) for on-highway motorcycle emissions certification and compliance'' to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below. The current ICR, under which on-highway motorcycles are included, is scheduled to expire on March 31, 2020. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before January 3, 2020.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OAR–2016–0027, to EPA online using EDOCKET (our preferred method), by email to *a-and-rdocket@epamail.epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Air and Radiation Docket, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Julian Davis, Environmental Protection Agency, 2000 Traverwood, Ann Arbor, MI 48105; telephone number: (734) 214–4029; fax number: (734) 214–4869; email address: *davis.julian@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has established a public docket for this ICR under Docket ID number EPA–HQ–OAR–2016–0027, which is available for public viewing at the Air and Radiation Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave. NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Air and Radiation Docket is (202) 566–1744. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above. Any comments related to this ICR should be submitted to EPA within 60 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov./edocket.*

Affected entities: Entities potentially affected by this action are on-highway motorcycle manufacturers and importers.

Title: Information Collection Request (ICR) for On-Highway Motorcycle Certification and Compliance Program.

Abstract: Under the Clean Air Act (42 U.S.C. 7521 *et seq.*) manufacturers and importers of on-highway motorcycles must have a certificate of conformity issued by EPA covering any vehicle they intend to offer for sale in the United States. A certificate of conformity represents that the respective vehicle conforms to all applicable emissions requirements. In issuing a certificate of conformity, EPA reviews vehicle information and emissions test data to determine if the required testing has been performed and the required emissions levels have been demonstrated. After a certificate of conformity has been issued, the Agency may request additional information to verify that the product continues to meet its certified emissions standards throughout its useful life. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9. The EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

EPA will consider the comments received and amend for the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

The current ICR for on-highway motorcycle emissions certification and compliance information is set to expire on March 31, 2019. This program was previously approved under the current ICR for highway motorcycle certification and compliance [EPA ICR No. 2535.01, OMB Control Number 2060–NEW].

Burden statement: EPA estimates that 70 respondents will submit information each year spending a total of 1,668,593 hours and incurring an annualized cost of 1.188 million dollars. The average burden per respondent varies greatly; it is a function of the diversity of the products produced or imported. (A large, diversified motor vehicle manufacturer will have a much greater burden than a small importer of a few identical vehicles.) Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency.

This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Form numbers: The EPA has developed forms, some of which are Excel-based, for the compliance programs in this ICR. Manufacturers may download these forms from EPA's website at *https://www.epa.gov/ve-certification/certification-non-electric-motorcycles* and submit these forms through the EPA's engine and vehicle compliance information system's (EV–CIS) document module. All of these forms are available for review in the Docket EPA–HQ–OAR–2016–0027.

Form title	New or previous	Current form No.
Highway Motorcycle HC+NO_X Average Exhaust Emissions Model Year Report	Previous	5900–339
Manufacturer Production Report for Engine/Equipment Manufacturers—Heavy-Duty, Nonroad, and Highway Motorcycles.	Previous	5900–90
List of Emissions Related Components	New	
Catalyst Information	Previous	5900–464

Respondents/affected entities: Entities potentially affected by this action are on-highway motorcycle manufacturers and importers.

Estimated number of respondents: 70.

Frequency of response: Quarterly and annually.

Estimated total annual hour burden: 5,453.

Estimated total annual cost: $1,188,628.31, which includes $18,680.00 annualized operation and maintenance costs, $42,664.00 annualized capital/startup costs, and $988,626.31 annual labor costs.

These estimates reflect an update to the previous cost estimates for on-highway motorcycles previously culled and compiled for the current ICR for highway motorcycle certification and compliance. Previously, we estimated more manufacturers that would maintain their own testing and certification facility. Currently, a larger percentage of manufacturers use contract test facilities and utilize carry over data for certification and compliance requirements.

Dated: October 24, 2019.

Byron J. Bunker,

Director, Compliance Division, Office of Transportation and Air Quality, Office of Air and Radiation.

[FR Doc. 2019–24067 Filed 11–1–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE: Thursday, November 7, 2019 at 10:00 a.m.

PLACE: 1050 First Street NE, Washington, DC (12th Floor).

STATUS: The November 7, 2019 Open Meeting has been canceled.

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Laura E. Sinram, Acting Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

Authority: Government in the Sunshine Act, 5 U.S.C. 552b.

Laura E. Sinram,

Acting Secretary and Clerk of the Commission.

[FR Doc. 2019–24173 Filed 10–31–19; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS19–08]

Appraisal Subcommittee Notice of Meeting

AGENCY: Federal Financial Institutions Examination Council.

ACTION: Notice of meeting.

Description: In accordance with Section 1104 (b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in open session for its regular meeting:

Location: Partnership for Public Service, 1100 New York Avenue NW, Suite 200 East, Washington, DC 20005.

Date: November 13, 2019.

Time: 10:00 a.m.

Status: Open.

Reports

Chairman
Executive Director
Delegated State Compliance Reviews
Grants Director
Financial Manager

Action and Discussion Items

August 28, 2019 Open Session Minutes
Grant Procedures Handbook
Appraisal Foundation FY20 Grant Proposals

How To Attend and Observe an ASC Meeting

If you plan to attend the ASC Meeting in person, we ask that you send an email to *meetings@asc.gov.* You may register until close of business November 8, 2019. The meeting space is intended to accommodate public attendees. However, if the space will not accommodate all requests, the ASC may refuse attendance on that reasonable basis. The use of any video or audio tape recording device, photographing device, or any other electronic or mechanical device designed for similar purposes is prohibited at ASC Meetings.

Dated: October 30, 2019.

James R. Park,

Executive Director.

[FR Doc. 2019–24050 Filed 11–1–19; 8:45 am]

BILLING CODE 6700–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Federal Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th and Constitution Avenue NW, Washington DC 20551–0001, not later than November 20, 2019.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Jerry A. Peplinski, Ubly, Michigan*; individually, as trustee of the Nicole Peplinski 2016 Northstar Irrevocable Trust and the Peplinski Family 2012 Trust to acquire voting shares of Northstar Financial Group, Inc. and thereby indirectly acquire Northstar Bank, both of Bad Axe, Michigan.

Frank A. Peplinski, trustee to the Frank A. Peplinski Trust dated June 14, 2017, David A. Peplinski and Marilyn R. Peplinski, trustees to the David A. Peplinski Trust dated April 17, 2017, Curtis Watchowski and Lynda Watchowski, trustees to the Brandon Watchowski 2017 Northstar Irrevocable Trust, Terry A. Peplinski, trustee to the Terry A. Peplinski Trust dated June 27, 2018, Lynda M. Watchowski, trustee to the Lynda M. Watchowski Trust dated May 30, 2018, Curtis Watchowski and Lynda Watchowski, trustees to the Jonathan Watchowski 2019 Northstar Irrevocable Trust, and a certain minor child, to be approved as members acting in concert with the Peplinski Family Control Group, and Jeffrey J. Roberts, trustee of the Jeffrey J. Roberts Trust dated December 29, 2016, to be approved as a member of the Roberts Family Control Group, all of Bad Axe, Michigan; to retain voting shares of Northstar Financial Group, Inc. and thereby indirectly retain Northstar Bank, both of Bad Axe, Michigan.

Board of Governors of the Federal Reserve System, October 30, 2019.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2019–24061 Filed 11–1–19; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th and Constitution Avenue, NW, Washington DC 20551–0001, not later than December 5, 2019.

A. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Adam Bank Group, Inc., College Station, Texas;* to acquire Security Star Bancshares, Inc., and thereby indirectly acquire Security Bank, both of Midland, Texas.

Board of Governors of the Federal Reserve System, October 29, 2019.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2019–24012 Filed 11–1–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–19BJD]

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 ''Monitoring and Reporting for the Overdose Data to Action Cooperative Agreement'' 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 July 25, 2019 to obtain comments from the public and affected agencies. CDC did not receive 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

Monitoring and Reporting for the Overdose Data to Action Cooperative Agreement—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This new data collection effort is to collect information from grantees

funded under the Overdose Data to Action (OD2A) cooperative agreement program. OMB approval is requested for three years.

Drug overdose deaths in the United States increased by 18% per year from 2014 to 2016. Opioid overdose deaths have increased five-fold from 1999 to 2016, and in 2017, there were more than 47,000 deaths attributed to opioids. In 2017, the opioid epidemic was declared a public health emergency by the U.S. Department of Health and Human Services (HHS).

The purpose of the Overdose Data to Action cooperative agreement program, administered by the Centers for Disease Control and Prevention (CDC), is to support state and local public health jurisdictions in obtaining high quality, complete, and timely data on opioid prescribing and overdoses, and to use this data to inform prevention and response efforts. There are two required components of this award: A surveillance component and a prevention component. The intent is to ensure that funded grantees are well equipped to do rigorous work under both components.

CDC requests OMB approval to collect information from 66 funded jurisdictions about the resources, plans, and activities needed to control the epidemic of fatal and nonfatal overdoses caused by opioids and other drugs. Awardees will submit to CDC an evaluation and performance measurement plan using a preformatted template; an organizational capacity assessment using an online tool; and an electronic activity progress report and work plan tool. Burden per response will be highest for the first year of funding during initial population of each electronic reporting form. In subsequent years, burden per response will decrease as awardees will only need to update the information requested on each form. CDC will also collect a one-time Surveillance Data Dissemination Plan which is not part of the annual reporting requirement.

The information collected will provide crucial data to CDC for program monitoring and budget tracking, to improve CDC-recipient communications, and to inform technical assistance and guidance documents produced by CDC to support program implementation among funded grantees. It will also provide CDC with the capacity to respond in a timely manner to requests for information about the program from HHS, the White House, Congress, and other sources. The data will be analyzed using descriptive, summary statistics, and qualitative summaries.

Participation in this information collection is required for funded awardees. There are no costs to the respondents other than their time. The total estimated annualized burden hours are 1,342.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Overdose Data to Action funded jurisdictions (State, territories, counties and cities) and their Designated Delegates.	Evaluation and Performance Measuring Plan Template—Initial Population.	22	1	12
	Evaluation and Performance Measuring Plan Template—Annual reporting.	66	1	4
	Organizational Capacity Assessment—Initial Population.	22	1	1
	Organizational Capacity Assessment—Annual Reporting.	66	1	1
	Activity Progress Report and Work Plan Tool—Initial Population.	22	1	20
	Activity Progress Report and Work Plan Tool—Annual Reporting.	66	1	4
	Surveillance Data Dissemination Plan Tool ...	22	1	1

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–23999 Filed 11–1–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–20–0841; Docket No. CDC–2019–0101]

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 Management Information Systems for Comprehensive Cancer Control Programs. This information collection aims to facilitate the monitoring of National Comprehensive Cancer Control Program awardee performance and submission of timely and accurate responses to inquiries from Congress and other stakeholders.

DATES: CDC must receive written comments on or before January 3, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0101 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: 404–639–7118; 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

Management Information Systems for Comprehensive Cancer Control Programs (OMB Control No. 0920–0841, Exp. 6/30/2019)—Reinstatement with Change—National Center for Chronic Disease and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 2017, 66 awardees, representing all 50 states, the District of Columbia, seven United States Association Pacific Islands and territories, and eight tribes and tribal organizations, were selected for funding under NOFO (DP171701DP17–1701, ''Cancer Prevention and Control Programs for State, Territorial, and Tribal Organizations''). Under this cooperative agreement, awardees implement cancer prevention and control programs to reduce cancer morbidity, mortality, and disparities. To facilitate program monitoring, performance assessment, and evaluation, a web-based management information system is needed for collection and abstraction of information about program resources, partnerships, work plan activities, and evaluation efforts.

CDC is requesting OMB approval for the continued use of the Management Information System to collect, store, retrieve, share, and report accurate and timely information. OMB approval is requested for the term of three years, which coincides with the last three years of the program. All 66 awardees will submit information on data elements in the Management Information System annually for a total estimated burden of 66 hours. Information collected will be analyzed and used in aggregate to describe program efforts. Participation is voluntary and there are no costs 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 hrs)	Total burden (in hrs)
Program Director for State-, Tribal-, or Territorial-based Cancer Preventionand Control Program.	Data Elements for All CPC Programs:Annual Reporting.	66	1	1	66
Total					66

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–24004 Filed 11–1–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–20–1181; Docket No. CDC–2019–0100]

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 Traveler Information Collection: Domestic Manifests and the Passenger Locator Form that enables CDC to collect contact information and facilitate public health follow-up of at-risk travelers in the event a sick person is confirmed on board an aircraft.

DATES: CDC must receive written comments on or before January 3, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0100 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 Traveler Information Collection: Domestic Manifests and the Passenger Locator Form (OMB Control No. 0920–1181, Exp. 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

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 timely, accurate, and complete 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 order to collect this contact information, (*i.e.,* a manifest), CDC is seeking approval for domestic airline and traveler information orders under current authorities in 42 Code of Federal Regulations (CFR) 70.10. This activity is already current practice.

CDC also requests continued approval to use the Passenger Locator Form (PLF) for the collection of traveler information from individuals on domestic flights and international flights under 42 CFR 70.10 and 42 CFR 71.20, respectively. The PLF, a form developed by the International Civil Aviation Organization (ICAO) in concert with its international member states and other aviation organizations, is used when there is a confirmation or strong suspicion that an individual(s) aboard a flight is infected with or exposed to a communicable disease that is a threat to co-travelers, and CDC is made aware of the individual(s) prior to arrival in the United States. This prior awareness can provide CDC with an opportunity to collect traveler contact information directly from the traveler prior to departure from the arrival airport.

CDC estimates that for each set of airline and traveler information ordered, airlines require approximately six hours to review the order, search their records, and send those records to CDC. CDC anticipates that travelers will need approximately five minutes to complete the PLF. There is no cost to respondents other than their time perform these actions. For manifest information, CDC does not have a specified format for these submissions, only that it is one acceptable to both CDC and the respondent.

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.	Domestic TB Manifest Template or Informal Manifest Request.	2	1	360/60	12
Airline Medical Officer or Equivalent/ Computer and Information Systems Manager.	Domestic Non-TB Manifest Template or Informal Manifest Request.	48	1	360/60	288
Traveler	Public Health Passenger Locator Form: Outbreak of public health significance* (international flights).	2,700,000	1	5/60	225,000
Traveler	Public Health Passenger Locator Form: Limited onboard exposure † (international flights).	800	1	5/60	67
Traveler	Public Health Passenger Locator Form (domestic flights).	800	1	5/60	67
Total					225,434

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–24006 Filed 11–1–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–20–0995; Docket No. CDC–2019–0097]

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 National Network of Sexually Transmitted Diseases Clinical Prevention Training Centers.'' The purpose of the collection is to support program management of the National Network of Sexually Transmitted Disease Clinical Prevention Training Center (NNPTC) and to evaluate the reach and impact of the NNPTC's training activities.

DATES: CDC must receive written comments on or before January 3, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0097 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

National Network of Sexually Transmitted Diseases Clinical Prevention Training Centers (NNPTC): Evaluation (OMB Control No. 0920–0995, Exp. 05/31/2020)—Extension—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), Division of STD Prevention requests an extension and three-year approval of the currently approved information collection request that comprises the NNPTC Abbreviated Health Professional Application for Training (NNPTC Abbreviated HPAT). This extension will allow the NNPTC Abbreviated HPAT to continue to serve as the official training application form used for training activities conducted by the Sexually Transmitted Disease (STD) Prevention Training Centers' (PTCs) grantees funded by the (CDC).

The PTCs are funded by CDC/Division of STD Prevention (DSTDP) to provide training and capacity-building that includes information, training, technical assistance and technology transfer. PTCs offer classroom and experiential training, web-based training, clinical consultation, and capacity building assistance to maintain and enhance the capacity of health care professionals to control and prevent STDs and HIV. The NNPTC Abbreviated HPAT is used to monitor and evaluate performance and reach of grantees that offer STD and HIV prevention training, training assistance, and capacity building assistance to physicians, nurses, disease intervention specialists, and health educators. During the previously approved three-year period, data was collected to monitor and evaluate the performance of the NNPTC grantees and the NNPTC program. This data provided the NNPTC with necessary information to improve program processes and operations in order to improve the quality of STD prevention and treatment.

The 4,500 respondents (who will engage in a total of 11,769 respondent instances) represent an average of the number of health professionals trained by PTC grantees during 2015. The evaluation instruments collect data on the impact of the training by the NNPTC. This data collection is necessary to assess and evaluate the performance of the grantees in delivering training and to standardize training registration processes across the PTCs. The NNPTC Abbreviated HPAT allows CDC grantees to use a single instrument when collecting demographic data from its training and capacity building participants, regarding their: (1) Occupations, professions, and functional roles; (2) principal employment settings; (3) location of their work settings; and (4) programmatic and population foci of their work. The NNPTC Abbreviated HPAT takes approximately three minutes to complete. This data collection provides CDC with information to determine whether the training grantees are reaching their target audiences in terms of provider type, the types of organizations in which participants work, the focus of their work and the population groups and geographic areas served.

The evaluation instruments are used to assess training and capacity-building outcomes (knowledge, confidence, intention to use information, actual changes made as a result of training) immediately after, and again 90 days after training events. The evaluation instruments vary based on the type of training offered and take between approximately 16 minutes (for intensive multi-day trainings) to two minutes to complete (for short didactic or webinar sessions).

The CDC's Funding Opportunity Announcement PS 14–1407, National Network of Sexually Transmitted Diseases Clinical Prevention Training Centers (NNPTC) requires the collection of national demographic information on grantees' trainees and national evaluation outcomes. There are no costs to respondents other than their time. The estimated annualized burden hours for this data collection are 502 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Healthcare Professionals	NNPTC Abbreviated Health Professional Application for Training (HPAT).	4,500	1	3/60	225
Healthcare Professionals	Intensive Complete Post-Course Evaluation.	116	1	16/60	31
	Intensive CompleteLong-TermEvaluation	36	1	10/60	6
Healthcare Professionals	Intensive-DidacticPost-CourseEvaluation	166	1	10/60	28
	Intensive-DidacticLong-TermEvaluation	58	1	7/60	7
Healthcare Professionals	PracticumPost-CourseEvaluation	70	1	4/60	5
	PracticumLong-TermEvaluation	20	1	3/60	1
Healthcare Professionals	Wet MountPost-CourseEvaluation	40	1	3/60	2
	Wet MountLong-TermEvaluation	15	1	2/60	1
Healthcare Professionals	STD Tx Guidelines Complete Post-CourseEvaluation.	548	1	6/60	55
	STD Tx Guidelines Complete Long-TermEvaluation.	180	1	5/60	15
Healthcare Professionals	Short GuidelinesPost-CourseEvaluation	500	1	3/60	25
	Short GuidelinesLong-Term Evaluation	160	1	3/60	8
Healthcare Professionals	BasicPost-CourseEvaluation	150	1	2/60	5
	BasicLong-Term Evaluation	50	1	2/60	2
Healthcare Professionals	Immediate Post-Course email invitation	4,500	1	1/60	75
Healthcare Professionals	3 Month Long-Term email invitation	660	1	1/60	11
Total					502

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–24005 Filed 11–1–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–20–20AZ; Docket No. CDC–2019–0099]

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 Evaluation of the Effectiveness of the Training and Education Modules in the North American Fatigue Management Program, which is an observational study evaluating 180 long-haul and regional truck drivers in a naturalistic driving study over eight months. Questionnaires, in-vehicle monitor system, Actigraphy devices, and smartphones will be used in the data collection.

DATES: CDC must receive written comments on or before January 3, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0099 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

Evaluation of the Effectiveness of the Training and Education Modules in the North American Fatigue Management Program—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The mission of the National Institute for Occupational Safety and Health (NIOSH) is to promote safety and health at work for all people through research and prevention. Reducing fatigue-related crashes is one of the top 10 changes needed to reduce transportation accidents and save lives identified by the National Transportation Safety Board (NTSB) for 2017–2018 and a National Occupational Research Agenda (NORA) priority.

Fatigue is a preventable cause of crashes. The North American Fatigue Management Program (NAFMP) was developed by the Federal Motor Carrier Safety Administration, Transport Canada, and other entities to address commercial motor vehicle (CMV) driver fatigue through a comprehensive approach that delivers prevention information to carriers, dispatchers, drivers, and family members. In 2015, the National Academy of Sciences published the report ''Commercial motor vehicle driver fatigue, long-term health, and highway safety research needs'' that identified the need for fully evaluating the NAFMP so that recommendations for implementation of NAFMP are supported by scientific evidence. NIOSH is collaborating with the FMCSA to ensure the success of the proposed study.

Data will be collected from CMV drivers (hereafter referred to as ''driver'') during their application to participate in the study, briefing session, study participation, and debriefing session. Data collection will primarily focus on driving performance, sleep, and sleepiness. These outcomes will be compared between pre-rollout of the NAFMP (in which drivers will operate as they did before their participation in the study) and after the rollout of the NAFMP training and education modules (in which drivers and managers will operate with increased knowledge, strategies, and techniques to reduce their fatigue). All drivers interested in participating in the study may complete the application. A briefing session will be scheduled with drivers who are found eligible for the study. During the briefing session, drivers who provide informed consent will be enrolled in the study. Drivers will have a debriefing session if a driver chooses to withdraw from the study early or upon completion of the eight-month participation period.

The sample of drivers in the study will include those employed as drivers at the participating carriers. Drivers who have a valid Class-A commercial driver's license (CDL) and work at the participating company in regional and

long-haul operations for at least one year will be eligible for the study. A convenience sample of 180 eligible drivers over a two-year period will be recruited to participate in the study. The study sample will include approximately 90 regional and 90 long-haul drivers. There will be no required minimum number of female or minority drivers to be included in the study.

Data will be collected during each phase: (1) In the application, drivers will be asked to provide their name and contact information (home address, telephone number, and email address) to allow contact from the research team regarding their eligibility for the study. (2) In the briefing session, drivers will be asked to complete the Background Questionnaire. (3) During the study, information collection will occur through several streams: (a) A real-time fatigue monitoring system installed in the participating driver's vehicle; (b) Smart phone apps to collect psychomotor vigilance test, Karolinska Sleepiness Scale, sleep log, difficulty of drive scale, degree of drive hazards scale, a fatigue scale, and a stress scale; (c) an electronic logging device to collect data on the driver's duty and driving; (d) a wrist actigraphy to collect data on driver sleep and wake times. Drivers will be asked to sync the actigraph with a smartphone app daily; (e) smartphone or web-based questionnaires including Exercise and Food Consumption Questionnaire, the quality of life short form 36 version-2 questionnaire (SF–36v2), Family Interactions Questionnaire, and Job Descriptive Index. These will be completed by drivers at four different intervals, including the beginning (first week) and middle (second month) of the baseline phase, and the middle (fifth month) and end (eighth month) of the intervention phase; (f) A questionnaire to assess corporate practices and corporate safety climate will be given to managers at the participating carriers. These will be completed by managers at the beginning (first week) of the study and end (eighth month) of the intervention phase; and (g) during the field study, carriers will be asked to provide information concerning crashes and roadside violations occurring during each driver's period of study participation. Administrative cost information (*e.g.,* equipment, labor, etc.) will also be collected from the carrier to evaluate cost-benefit of the intervention. The total annualized burden hours requested is 5,139.

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 hours (in hours)
Carrier Management	Participation Agreements	1	1	1	1
	Monthly Roadside Violations, ELD, Crash Reports, Administrative Costs.	1	16	30/60	8
	Corporate Practices Questionnaire	10	1	45/60	8
Drivers	Application to Participate	150	1	12/60	30
	Actigraph Training	90	1	10/60	15
	Background Questionnaire	90	1	45/60	68
	Daily Smartphone Questions	90	720	1/60	1,037
	PVT	90	720	3/60	3,240
	Exercise and Food Consumption Questionnaire.	90	4	20/60	120
	SF–36v2	90	4	30/60	180
	Family Interactions Questionnaire	90	4	15/60	90
	Job Descriptive Index	90	4	30/60	180
	Post-Study Questionnaire	90	1	1	90
	Phone Briefings	90	8	6/60	72
Total					5,139

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–24002 Filed 11–1–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–19DO]

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 National Surveillance of Community Water Systems and Corresponding Populations with the Recommended Fluoridation Level 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 December 6, 2018 to obtain comments from the public and affected agencies. CDC received two 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 agencie's 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

National Surveillance of Community Water Systems and Corresponding Populations with the Recommended Fluoridation Level—Existing Collection in use without an OMB Control Number—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Dental caries is one of the most common chronic diseases throughout the lifespan in the United States, and disproportionately affects populations with low socioeconomic status, and racial and ethnic minority populations. Dental caries can lead to infection and diminished quality of life, and cause substantial societal cost due to absence from school and work, as well as expensive treatments. Naturally occurring fluoride is found in all surface and ground water sources, but typically is lower than the recommended concentration needed to prevent dental caries (tooth decay). Community water fluoridation is the process of adjusting the fluoride concentration of a community water system (CWS) to the level beneficial for prevention of dental caries as recommended by the US Public Health Service (PHS). CDC monitors CWS fluoride levels relative to the PHS recommended level under the Public Health Service Act.

In 2000, CDC launched a Web-based data management tool—Water Fluoridation Reporting Systems (WFRS) in collaboration with the Association of State and Territorial Dental Directors. States may report their information to CDC using WFRS or via email. Respondents to the information collection are state fluoridation managers or other state government officials designated by the state dental director or drinking water administrator. Respondents are asked to update fluoridation status of, and counties and populations served by, each CWS in their state annually. All 50 states respond to this portion of the collection. Washington DC is not included in the data collection because water is supplied by a CWS from Virginia and therefore the data is collected by Virginia. Historically collected natural fluoride concentrations are available in WFRS for all CWS; once collected, they rarely change over time. Respondents also are asked to enter the high, low, and average fluoride testing level data annually for each month for their fluoride-adjusted CWS. Currently, two-thirds of the states respond to this portion of the collection.

CDC analyzes and publishes results through interactive, public-facing web pages: (1) Biennial surveillance reports documenting the percentage of the population with fluoridated water at national, state, and local levels; and (2) My Water's Fluoride, which publishes the fluoridation status of individual CWS and some fluoride level data for states which choose to display it.

CDC uses the information collection to (1) provide national fluoridation surveillance reports; (2) assist states to manage their fluoride level data and monitor and improve quality of community water fluoridation programs; (3) measure national performance toward the fluoridation Healthy People objective; (4) evaluate outcomes of CDC's cooperative agreements with states; (5) facilitate creation of state-specific reports for states' programmatic and policy use. The information collection is also used to inform health care providers to determine targeted delivery of preventive care, for example, determining use of fluoride supplements for children living in fluoride-deficient areas.

CDC's collection of CWS data is not duplicative of any other federal collection, including the US Environmental Protection Agency's (EPA) Safe Drinking Water Information System (SDWIS), as SDWIS receives state reports of CWS fluoride levels that exceed 4 mg/L but not those near the beneficial level of 0.7 mg/L recommended for dental caries prevention by the PHS. Thus, CDC's system is required to assess the degree to which the nation is reaching this PHS-recommended level. The total estimated annualized burden hours are 2,783, including (1) 1,875 hours for the validation or update of CWS fluoridation status and population served from 50 respondents, with estimated average burden hours of 37.5 per respondent; and (2) 908 hours for the annual entry of fluoride testing level data for fluoride-adjusted CWS conducted by 33 respondents with an estimated average burden of 27.5 hours per respondent. WFRS is hosted and maintained by CDC and there are no maintenance costs to respondents.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State Official	Fluoridation status and population	50	1	37.5
State Official	Fluoride testing data	33	1	27.5

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–24000 Filed 11–1–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–0255]

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 ''Resources and Services Database of the CDC National Prevention Information Network (NPIN)'' 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 July 5, 2019 to obtain comments from the public and affected agencies. CDC did not receive 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

Resources and Services Database of the CDC National Prevention Information Network (NPIN) (OMB Control No. 0920–0255, Exp. 02/29/2020)—Revision—National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NCHHSTP has the primary responsibility within the CDC and the U.S. Public Health Service for the prevention and control of HIV infection, viral hepatitis, sexually transmitted diseases (STDs), and tuberculosis (TB), as well as for community-based HIV prevention activities, syphilis, and TB elimination programs. This request is for a revision and three-year approval of a currently approved data collection under the Paperwork Reduction Act. This data collection is currently approved under OMB Control No. 0920–0255. The purpose of this data collection is to assist the public by providing information about resources.

The National Prevention Information Network (NPIN) serves as the U.S. reference, referral, and distribution service for information on HIV/AIDS, viral hepatitis, STDs, and TB, supporting NCHHSTP's mission to link Americans to prevention, education, and care services. If NPIN does not continue this information collection and verification project, the potential number of resource listings will be significantly reduced, and the accuracy and currency of the existing records will be greatly diminished. The NPIN Resources and Services Database contains entries on approximately 10,000 organizations and is the most comprehensive listing of HIV/AIDS, viral hepatitis, STD, and TB resources and services available throughout the country. The American public can access the NPIN resources and Services database through the NPIN website. More than 1,000,000 unique visitors and more than 3,000,000 page views are recorded annually.

Information for this request will be collected using the Resources and Services Questionnaire. Organizations with access to the internet will be given the option to complete and submit an electronic version of the questionnaire by visiting the NPIN website. Methods to be used to collect the information include online, telephone and email survey questionnaires to collect information from representatives of the organizations that provide covered services. In comparison to the previously approved collection, the NPIN questionnaire is collecting the same information, but the format of the NPIN online questionnaire was modified to decrease free text. This serves to improve the time needed to complete the form. To accomplish CDC's goal of continuing efforts to maintain an up-to-date, comprehensive database, NPIN plans each year to add up to 400 newly identified organizations and verify those organizations currently described in the NPIN Resources and Services Database each year. Updates to the NPIN resources and services questionnaire reduced the total burden hours by 33% when compared to the previous OMB clearance. This data collection uses no inferential statistical methods. The data collected is in textual or anecdotal format and will be used for information purposes. There are no costs to respondents other than their time. The total burden is 1,144 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Form	Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Initial Questionnaire Telephone Script.	Registered nurses, Social and community service managers, and Health educators.	400	1	8/60
Telephone Verification	Registered nurses, Social and community service managers, and Health educators Social and human service assistants.	6,100	1	6/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form	Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Email Verification	Registered nurses, Health educators, and Social and human service assistants, social and community service managers.	3,600	1	8/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–24001 Filed 11–1–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–20–0728; Docket No. CDC–2019–0096]

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 ''*The National Notifiable Diseases Surveillance System (NNDSS).*'' *The NNDSS is the nation's public health surveillance system that monitors the occurrence and spread of diseases and conditions that are nationally notifiable or under standard surveillance.*

DATES: CDC must receive written comments on or before January 3, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0096 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

National Notifiable Diseases Surveillance System (NNDSS)—Revision—Center for Surveillance, Epidemiology and Laboratory Services (CSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Public Health Services Act (42 U.S.C. 241) authorizes CDC to disseminate nationally notifiable condition information. The National Notifiable Diseases Surveillance System (NNDSS) is based on data collected at the state, territorial and local levels as a result of legislation and regulations in those jurisdictions that require health care providers, medical laboratories, and other entities to submit health-related data on reportable conditions to public health departments. These reportable conditions, which include infectious and non-infectious diseases, vary by jurisdiction depending upon each jurisdiction's health priorities and needs. Each year, the Council of State and Territorial Disease Epidemiologists (CSTE), supported by CDC, determines which reportable conditions should be designated nationally notifiable or under standardized surveillance.

CDC requests a three-year approval for a Revision to the NNDSS (OMB Control No. 0920–0728, Expiration Date 04/30/2022). This Revision includes requests for approval to: (1) Receive case notification data for Blastomycosis which is now under standardized surveillance; and (2) receive disease-specific data elements for Carbon Monoxide (CO) Poisoning, Congenital Syphilis, and Sexually Transmitted Disease (STD, not congenital).

The NNDSS currently facilitates the submission and aggregation of case notification data voluntarily submitted to CDC from 60 jurisdictions: Public health departments in every U.S. state,

New York City, Washington DC, five U.S. territories (American Samoa, the Commonwealth of Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands), and three freely associated states (Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau). This information is shared across jurisdictional boundaries and both surveillance and prevention and control activities are coordinated at regional and national levels.

Approximately 90% of case notifications are encrypted and submitted to NNDSS electronically from already existing databases by automated electronic messages. When automated transmission is not possible, case notifications are faxed, emailed, uploaded to a secure network or entered into a secure website. All case notifications that are faxed, emailed, and uploaded are done so in the form of an aggregate weekly or annual report, not individual cases. These different mechanisms used to send case notifications to CDC vary by the jurisdiction and the disease or condition. Private personally identifiable information (PII) is collected from automated electronic messages and information can be retrieved by PII. In addition, some combinations of submitted data elements could potentially be used to identify individuals. Private information is not to be disclosed unless otherwise compelled by law. All data are treated in a secure manner consistent with the technical, administrative, and operational controls required by the Federal Information Security Management Act of 2002 (FISMA) and the 2010 National Institute of Standards and Technology (NIST) Recommended Security Controls for Federal Information Systems and Organizations. Weekly tables of nationally notifiable diseases are available through CDC WONDER and *data.cdc.gov*. Annual summaries of finalized nationally notifiable disease data are published on CDC WONDER and *data.cdc.gov* and disease-specific data are published by individual CDC programs.

The burden estimates include the number of hours that the public health department uses to process and send case notification data from their jurisdiction to CDC. Specifically, the burden estimates include separate burden hours incurred for automated and non-automated transmissions, separate weekly burden hours incurred for modernizing surveillance systems as part of NNDSS Modernization Initiative (NMI) implementation, separate burden hours incurred for annual data reconciliation and submission, and separate one-time burden hours incurred for the addition of new diseases and data elements. The burden estimates for the one-time burden for reporting jurisdictions for the addition of case notification data for Blastomycosis and disease-specific data elements for CO Poisoning, Congenital Syphilis, and Sexually Transmitted Disease (not congenital). The estimated annual burden for the 257 respondents is 18,354 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 (in hours)
States	Weekly (Automated)	50	52	20/60	867
States	Weekly (Non-automated)	10	52	2	1,040
States	Weekly (NMI Implementation)	50	52	4	10,400
States	Annual	50	1	75	3,750
States	One-time Addition of Diseases and Data Elements.	50	1	2	100
Territories	Weekly (Automated)	5	52	20/60	87
Territories	Weekly, Quarterly (Non-automated)	5	56	20/60	93
Territories	Weekly (NMI Implementation)	5	52	4	1,040
Territories	Annual	5	1	5	25
Territories	One-time Addition of Diseases and Data Elements.	5	1	2	10
Freely Associated States	Weekly (Automated)	3	52	20/60	52
Freely Associated States	Weekly, Quarterly (Non-automated)	3	56	20/60	56
Freely Associated States	Annual	3	1	5	15
Freely Associated States	One-time Addition of Diseases and Data Elements.	3	1	2	6
Cities	Weekly (Automated)	2	52	20/60	35
Cities	Weekly (Non-automated)	2	52	2	208
Cities	Weekly (NMI Implementation)	2	52	4	416
Cities	Annual	2	1	75	150
Cities	One-time Addition of Diseases and Data Elements.	2	1	2	4
Total					18,354

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–24003 Filed 11–1–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4986]

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Cardiovascular and Renal Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on December 10, 2019, from 8 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2019–N–4986. The docket will close on December 9, 2019. Submit either electronic or written comments on this public meeting by December 9, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 9, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 9, 2019. 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.

Comments received on or before November 25, 2019, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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–N–4986 for ''Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' 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.'' FDA 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 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 the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Yinghua S. Wang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *CRDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute

modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will be asked to discuss new drug application (NDA) 022034, for vernakalant HCl solution, for intravenous injection, submitted by Correvio International Sàrl, for the proposed indication of rapid conversion of recent onset atrial fibrillation to sinus rhythm for non-surgery patients: Atrial fibrillation ≤7 days duration, and for post-cardiac surgery patients: Atrial fibrillation ≤3 days duration.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see the **ADDRESSES** section) on or before November 25, 2019, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 15, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 18, 2019.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Yinghua S. Wang (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23978 Filed 11–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Infant Mortality

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Secretary's Advisory Committee on Infant Mortality (ACIM or Committee) has scheduled a public meeting. Information about ACIM and the agenda for this meeting can be found on the ACIM website at *https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

DATES: December 4–5, 2019, 9:00 a.m.–5:00 p.m. Eastern Time (ET).

ADDRESSES: This meeting will be held in-person and via webinar. The address for the meeting is 5600 Fishers Lane, Rockville, Maryland 20857.

- *The webinar link will be available at ACIM's website: https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*
- *The conference call-in number will be available at ACIM's website: https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

FOR FURTHER INFORMATION CONTACT: David S. de la Cruz, Ph.D., MPH, Designated Federal Official, (DFO), Maternal and Child Health Bureau (MCHB), HRSA, 5600 Fishers Lane, Room 18N25, Rockville, Maryland 20857; at 301–443–0543 or *dcruz@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The ACIM advises the Secretary of HHS on department activities and programs directed at reducing infant mortality and improving the health status of pregnant women and infants. The ACIM represents a public-private partnership at the highest level to provide guidance and focus attention on the policies and resources required to address the reduction of infant mortality and the improvement of the health status of pregnant women and infants. With a focus on life course, the ACIM addresses disparities in maternal health to improve maternal health outcomes, including preventing and reducing maternal mortality and severe maternal morbidity. The ACIM provides advice on how best to coordinate the myriad of federal, state, local, and private programs and efforts that are designed to deal with the health and social problems impacting infant mortality and maternal health, including implementation of the Healthy Start program and maternal and infant health objectives from the National Health Promotion and Disease Prevention Objectives. The ACIM is authorized by section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended. The Committee is governed by provisions of Public Law 92–463, as amended, (5 U.S.C. App. 2), which sets forth standards for the formation and use of Advisory Committees.

The agenda for the December 4–5, 2019, meeting is being finalized and may include the following: Updates from the HRSA Maternal and Child Health Bureau (MCHB), Centers for Disease Control and Prevention, and the MCHB Healthy Start program; introduction of members; briefing on infant mortality and health disparity data in the U.S.; the Prematurity Research Expansion and Education for Mothers who deliver Infants Early (PREEMIE) Act; and discussions on future topics areas for ACIM to address. Agenda items are subject to change as

priorities dictate. The final meeting agenda will be available 2 days prior to the meeting on the Committee's website: *https://www.hrsa.gov/advisory-committees/Infant-Mortality/index.html.*

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to the ACIM should be sent to David S. de la Cruz, DFO, using the contact information above at least 3 business days prior to the meeting.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify David S. de la Cruz at the address and phone number listed above at least 10 business days prior to the meeting. Since this meeting occurs in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2019–24060 Filed 11–1–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; STIMULATE: T4 Implementation Research for HLBS Diseases and Disorders.

Date: December 10, 2019.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National, Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892, *susan.sunnarborg@nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI Mentored Career Development Awards—K01, K08, K23.

Date: December 16, 2019.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lindsay M. Garvin, Ph.D., Scientific Review Officer, Office of Scientific Review, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Suite 7189, Bethesda, MD 20892, 301–827–7911, *lindsay.garvin@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 29, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23991 Filed 11–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Endocrinology, Metabolism and Nutrition.

Date: November 20, 2019.

Time: 1:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Gregory S. Shelness, Ph.D., Scientific Review Officer Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6156, Bethesda, MD 20892–7892, (301) 435–0492, *shelnessgs@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–HL–20–005: Late-Stage Implementation Research Addressing Hypertension in Low and Middle-Income Countries: Scaling Up Proven-Effective Interventions.

Date: November 21, 2019.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Brian H. Scott, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–827–7490, *brianscott@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel RFA–HL–20–005: Late-Stage Implementation Research Addressing Hypertension in Low- and Middle-Income Countries: Scaling Up Proven-Effective Interventions.

Date: November 21, 2019.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 237–9838, *bhagavas@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Toxicology and Digestive, Kidney and Urological Systems AREA/REAP Review.

Date: November 21, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Aiping Zhao, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2188, MSC 7818, Bethesda, MD 20892–7818, (301) 435–0682, *zhaoa2@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Gastroenterology.

Date: November 21–22, 2019.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Nuria E. Assa-Munt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892, (301) 451–1323, *assamunu@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Vaccines Against Microbial Diseases.

Date: November 21, 2019.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Andrea Keane-Myers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4218, Bethesda, MD 20892, (301) 435–1221, *andrea.keane-myers@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–OD–19–020: Building Interdisciplinary Research Careers in Women's Health K12s.

Date: November 21–22, 2019.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, EMNR IRG Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6182, MSC 7892, Bethesda, MD 20892, (301) 435–2514, *riverase@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cardiovascular Sciences.

Date: November 21, 2019.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Chee Lim, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4128 , Bethesda, MD 20892, (301) 435–1850, *limc4@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Mammalian Models for Translational Research.

Date: November 21, 2019.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892 (Regular Meeting).

Contact Person: Jeffrey Smiley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, (301) 594–7945, *smileyja@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Urology and Urogynecology Application Review.

Date: November 21, 2019.

Time: 1:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Julia Spencer Barthold, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402–3073, *julia.barthold@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Cell Biology.

Date: November 21, 2019.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: John Burch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 3213, MSC 7808, Bethesda, MD 20892, (301) 408–9519, *burchjb@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: Tobacco Regulatory Science A.

Date: November 21, 2019.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jasenka Borzan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892–7814, (301) 435–1787, *borzanj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Therapeutic Approaches to Genetic Disease.

Date: November 21, 2019.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Baishali Maskeri, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2022, Bethesda, MD 20892, (301) 827–2864, *maskerib@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Child Psychopathology and Developmental Disabilities.

Date: November 21, 2019.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Serena Chu. Ph.D., Scientific Review Officer, BBBP IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3178, MSC 7848, Bethesda, MD 20892, (301) 500–5829, *sechu@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Electronic Nicotine Delivery Systems: Basic Mechanisms of Health Effects-PAR Panel.

Date: November 21–22, 2019.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ghenima Dirami, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7814, Bethesda, MD 20892, (240) 498–7546, *diramig@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 29, 2019.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23994 Filed 11–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR–18–423: NIDDK Multi-Center Clinical Study Implementation Planning Cooperative Agreements (U34).

Date: November 18, 2019.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, National Institutes of Health, Room 7119, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–2242, *jerkinsa@niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: October 29, 2019.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23996 Filed 11–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; NHLBI Institutional Training Mechanism Review Committee.

Date: December 13, 2019.

Time: 9:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lindsay M. Garvin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Suite 7189, Bethesda, MD 20892, 301–827–7911, *lindsay.garvin@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 29, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23997 Filed 11–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License for: Autologous Cell Graft of Manufactured Retinal Pigment Epithelium Cell(s) on a Biodegradable Support Scaffold Transplanted Sub-Retinally for Intra-Ocular Ophthalmic Treatment of Age-Related Macular Degeneration in Humans

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Eye Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to CellRay, LLC, (''CellRay'') located in New York, New York and its affiliates.

DATES: Only written comments and/or complete applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before November 19, 2019 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Edward Fenn., Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892–9702 (for business mail), Rockville, MD 20850–9702; Telephone: (240)-276–5530; Facsimile: (240)-276–5504 Email: *Tedd.Fenn@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

- PCT Patent App. No. PCT/US2015/039932, filed 07/10/15 (NIH Ref. E–192–2014–1–PCT–01); United States Patent App. No. 15/325,584, filed 01/11/17 (NIH Ref. E–192–2014–1–US–02); Australia Patent App. No. 2015287692, filed 07/10/15 (NIH Ref. E–192–2014–1–AU–03); Canada Patent App. No. 2954762, filed 07/10/15 (NIH Ref. E–192–2014–1–CA–04); PEC Patent App. No. 15741462.4, filed 07/10/15 (NIH Ref. E–192–2014–1–EP–05); India Patent App. No. 21717003244, filed 01/30/17 (NIH Ref. E–192–2014–1–IN–06); Japan Patent App. No. 2017–501212 Filed 01/10/17 (NIH Ref. E–192–2014–1–JP–07); each entitled ''Surgical Tool and Method for Ocular Tissue Transplantation''
- United States Patent App. No. 62/215,579, filed 09/08/15 (NIH Ref. E–212–2015–0–US–01); PCT Patent App. No. PCT/US2016/050543, filed 09/07/16 (NIH Ref. E–212–2015–0–PCT–02); United States Patent App. No. 15/758,314, filed 03/07/18 (NIH Ref. E–212–2015–0–US–07); each entitled ''Method for Reproducible Differentiation of Clinical-Grade Retinal Pigment Epithelium Cells''
- United States Provisional Patent App. No. 62/419,804, filed 11/09/16 (NIH Ref. E–293–2016–0–US–01); PCT Patent App. No. PCT/US2017/060672, filed 11/08/17 (NIH Ref. E–293–2016–0–PCT–02); Australia Patent App. No. 2017359336, filed 11/08/17 (NIH Ref. E–293–2016–0–AU–04); Canada Patent App. No. 3043174, filed 11/08/17 (NIH Ref. E–293–2016–0–CA–05); EPC Patent App. No. 17801272.0, filed 11/08/17 (NIH Ref. E–293–2016–0–EP–06); Japan Patent App. No. 2017–545900 (NIH Ref. E–293–2016–0–JP–07); United States Patent App. No. 16/348,855, filed 05/09/2019 (NIH Ref. E–293–2016–0–US–03); each entitled ''A Surgical Clamp to Gate Large Scleral Surgery Port and Suture Alignment Tool'';
- United States Patent App. No. 62/453,148, filed 02/01/17 (NIH Ref. E–094–2016–0–US–01); PCT Patent App. No. PCT/US2018/016101, Filed 01/31/18 (NIH Ref. E–094–2016–0–PCT–02) entitled ''Devices for Tissue Cryopreservation and Recovery'' and; United States Patent App. No. 16/478,093 (NIH Ref. E–094–2016–0–US–03); Australia Patent App. No. 2018214954 filed 01/31/18 (NIH Ref. E–094–2016–0–AU–04); Canada Patent App. No. 3048523 (NIH Ref. E–094–2016–0–CA–05); EPC Patent App. No. 18704773.3 (NIH Ref. E–094–2016–0–EP–06); Japan Patent App. No. 2019–538157 (NIH Ref. E–094–2016–0–JP–07); each ''A Self-contained

Cryopreservation and Recovery Device for Tissue Storage, Shipping and Recovery''

• United States Patent App. No 62/769,484, filed 11/19/18 (NIH Ref. E–015–2019–0–US–01) entitled ''Biodegradable Tissue Replacement Implant and its Use'';

and all U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be limited to the United States for certain of the rights, or worldwide, and the field of use may be limited to the following:

''The development, production and commercialization of an autologous cell graft of manufactured Retinal Pigment Epithelium cell(s) on a biodegradable support scaffold transplanted sub-retinally for intra-ocular ophthalmic treatment of age-related macular degeneration in humans''.

The technologies relate to development of compositions, devices and processes for production and delivery of RPE-containing tissue graft therapies for treating age-related macular degeneration in humans.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a completed license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: October 24, 2019.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2019–23995 Filed 11–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License for: Ointments for the Topical Administration To Treat Neuropathic and/or Ischemic Skin Ulcers in Humans

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Clinical Center and National Heart Lung and Blood Institute, each an institute of the National Institutes of Health, Department of Health and Human Services, are contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to TeamedOn International Inc., (''TeamedOn''), a Delaware corporation with offices in Gaithersburg, Maryland.

DATES: Only written comments and/or complete applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before November 19, 2019 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Edward Fenn., Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892–9702 (for business mail), Rockville, MD 20850–9702; Telephone: (240) 276–5530; Facsimile: (240) 276–5504 Email: *Tedd.Fenn@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

I. United States Provisional Patent Application No. 62/077,622 filed Nov. 10, 2014, ''Topical Sodium Nitrite Formulations'', [HHS Ref. No. E–149–2014–0–US–01];

II. International Patent Application No. PCT/US2015/060015 filed Nov. 10, 2015, ''Topical Sodium Nitrite Formulations'', [HHS Reference No. E–149–2014–0–PCT–02];

III. European National Stage Patent Application No. 15798623.3, filed Nov. 10, 2015, ''Topical Sodium Nitrite Formulations'', [HHS Ref. No. E–149–2014–0–EP–03];

IV. U.S. National Stage Patent Application No. 15/525,557 filed May 9, 2017, ''Topical Sodium Nitrite Formulations'', [HHS Ref. No. E–149–2014–0–US–04];

and all U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be limited to the United States for certain of the rights, or worldwide, and the field of use may be limited to the following:

''Treatment of neuropathic and/or ischemic skin ulcers in human.

The technology relates to topical ointment formulations comprising about .5% to 3.0% by weight non-acidified sodium nitrite dispersed in white petrolatum, mineral oil and bisabolol for topical administration. Nitrite anions may act as a vasodilator in vivo by generating nitric oxide (NO) in tissues with lower oxygen tension and pH. Therapeutic application of sodium nitrite through this specific topical formulation may provide selective vasodilation to hypoxemic tissue that treat ulcers associated with chronic ischemic and neuropathic ulcer conditions associated with several diseases.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a completed license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: October 24, 2019.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2019–23993 Filed 11–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 Advisory Board on Medical Rehabilitation Research.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Advisory Board on Medical Rehabilitation Research.

Date: December 2–3, 2019.

Time: December 02, 2019, 9:00 a.m. to 5:00 p.m.

Agenda: NCMRR Director's report; Update on NIH Helping to End Addiction Long-term [HEAL] Initiative; NICHD Director's report; Discussion of Career Development and K12 Networks; Progress on the current 2018 NIH Rehabilitation Research Plan; Subcommittee Reports: Planning for the NIH Rehabilitation Research Conference and update on the next NIH Rehabilitation Research Plan.

Place: NICHD Offices, 6710B Rockledge Drive, Rooms 1425/1427, Bethesda, MD 20892.

Time: December 03, 2019, 8:30 a.m. to 12:00 p.m.

Agenda: Update on NIH Pathways to Prevention Initiative; Teaming with Participants to Improve the Validity and Rigor of Rehabilitation Research; Scientific presentation on Precision Medicine in Pediatric Rehabilitation; Concept Clearance.

Place: NICHD Offices, 6710B Rockledge Drive, Rooms 1425/1427 Bethesda, MD 20892.

Contact Person: Ralph M. Nitkin, Ph.D., Director, B.S.C.D., Biological Sciences and Career Development, NCMRR, Eunice Kennedy Shriver National Institute of Child Health & Human Development, NIH, DHHS, 6100 Executive Boulevard, Room 2A03, Bethesda, MD 20892–7510, (301) 402–4206, *nitkinr@mail.nih.gov*.

Information is also available on the Institute's/Center's home page: *www.nichd.nih.gov/about/ncmrr.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: October 29, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23992 Filed 11–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; Heart, Lung, and Blood Program Project Review Committee.

Date: December 6, 2019.

Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Jeffrey H. Hurst, Ph.D., Scientific Review Officer Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7208, Bethesda, MD 20892, 301–435–0303. *hurstj@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 29, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23998 Filed 11–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2019–0876]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0066

AGENCY: Coast Guard, DHS.

ACTION: Sixty-Day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0066, Vessel and Facility Response Plans (Domestic and Int'l), and Additional Response Requirements for Prince William Sound; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before January 3, 2020.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2019–0876] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains

information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. Consistent with the requirements of Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs, and Executive Order 13777, Enforcing the Regulatory Reform Agenda, the Coast Guard is also requesting comments on the extent to which this request for information could be modified to reduce the burden on respondents.

In response to your comments, we may revise the this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2019–0876], and must be received by January 3, 2020.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Information Collection Request

Title: Vessel and Facility Response Plans (Domestic and Int'l), and Additional Response Requirements for Prince William Sound.

OMB Control Number: 1625–0066.

Summary: The Oil Pollution Act of 1990 (OPA 90) required the development of Vessel and Facility Response Plans to minimize the impact of oil spills. OPA 90 also required additional response requirements for Prince William Sound. Shipboard Oil Pollution Emergency Plans and Shipboard Marine Pollution Emergency Plans are required of other vessels to minimize impacts of oil spills.

Need: This information is needed to ensure that vessels and facilities are prepared to respond in event of a spill incident. The information is reviewed by the Coast Guard to assess the effectiveness of the reponse plan.

Forms: N/A.

Respondents: Owners and operators of vessels and facilities.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 75,380 hours to 88,381 hours a year, due to an increase in the estimated annual number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: October 30, 2019.

James D. Roppel,

Chief, U.S. Coast Guard, Office of Information Management.

[FR Doc. 2019–24025 Filed 11–1–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2019–0262]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0056

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the collection of information classified under OMB Control Number 1625–0056; without change. This collection of information is used for issuing vessel serial numbers and labels for the following: Hull Identification Numbers; U.S. Coast Guard Maximum Capacities; Gasoline Fuel Tank; USCG Type Fuel Hose and Certified Navigation Light Labels. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before December 4, 2019.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2019–0262] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* Alternatively, you may submit comments to OIRA using one of the following means:

(1) *Email: OIRA-submission@omb.eop.gov.*

(2) *Mail:* OIRA, 725 17th Street NW, Washington, DC 20503, attention Desk Officer for the Coast Guard.

(3) *Fax:* 202–395–6566. To ensure your comments are received in a timely manner, mark the fax, attention Desk Officer for the Coast Guard.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of

the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. Consistent with the requirements of Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs, and Executive Order 13777, Enforcing the Regulatory Reform Agenda, the Coast Guard is also requesting comments on the extent to which this request for information could be modified to reduce the burden on respondents. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG–2019–0262], and must be received by December 4, 2019.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

OIRA posts its decisions on ICRs online at *http://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0056.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard has published the 60-day notice (84 FR 42938, August 19, 2019) required by 44 U.S.C. 3506(c)(2). That notice elicited one comment that stated, ''to check all policy by the owner/government policy to register to show more penalties from act of government'' which does not provide any suggestions for improving this collection of information. Accordingly, no changes have been made to the Collections.

Information Collection Request

Title: Labeling required in 33 CFR parts 181 and 183 and 46 CFR 25.10–3.

OMB Control Number: 1625–0056.

Summary: Parts 181 and 183 of Title 33, Code of Federal Regulations and 46 CFR 25.10–3 contain the regulations and safety standards authorized by the statutes which apply to manufacturers of recreational boats, un-inspected commercial vessels and associated equipment. The regulations and safety standards contain information collections, which require boat and associated equipment manufacturers, importers and the boating public to apply for serial numbers and to display various labels evidencing compliance: Hull Identification Numbers; U.S. Coast Guard Maximum Capacities Label; Gasoline Fuel Tank Label; USCG Type Fuel Hose Label; and Certified Navigation Light Label.

Need: Title 46 U.S.C. 4302(a)(3) gives the Coast Guard the authority to require the display of seals, labels, plates, insignia, or other devices for certifying or evidencing compliance with safety regulations and standards of the United States Government for recreational vessels and associated equipment.

Forms: CG–9070, Application for Manufacturer Identification Code (MIC).

Respondents: Manufacturers of boats, fuel tanks, fuel hoses and navigation lights.

Frequency: Once.

Hour Burden Estimate: The estimated burden has increased from 204,996 hours to 216,144 hours a year, due to the estimated annual number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: October 30, 2019.

James D. Roppel,

Chief, U.S. Coast Guard, Office of Information Management.

[FR Doc. 2019–24023 Filed 11–1–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2019–0703]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–NEW

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval for the following collection of information: 1625–NEW, Intermodal Container Inspection Program. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before December 4, 2019.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2019–0703] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* Alternatively, you may submit comments to OIRA using one of the following means:

(1) *Email: OIRA-submission@omb.eop.gov.*

(2) *Mail:* OIRA, 725 17th Street NW, Washington, DC 20503, attention Desk Officer for the Coast Guard.

(3) *Fax:* 202–395–6566. To ensure your comments are received in a timely manner, mark the fax, attention Desk Officer for the Coast Guard.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–612), ATTN: PAPERWORK REDUCTION ACT

MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE SE, STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection. The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. Consistent with the requirements of Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs, and Executive Order 13777, Enforcing the Regulatory Reform Agenda, the Coast Guard is also requesting comments on the extent to which this request for information could be modified to reduce the burden on respondents. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG–2019–0703], and must be received by December 4, 2019.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

OIRA posts its decisions on ICRs online at *http://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–NEW.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard has published the 60-day notice (84 FR 42940, August 19, 2019) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments. Accordingly, no changes have been made to the Collections.

Information Collection Request

Title: Intermodal Container Inspection Program.

OMB Control Number: 1625–NEW.

Summary: The Coast Guard inspects containers and cargo within containers to ensure compliance with domestic and international standards. Coast Guard-issued forms provide stakeholders with the results of container examinations.

Need: Under the National Container Inspection Program, Coast Guard personnel inspect intermodal containers and cargo within containers to ensure compliance with applicable regulations and to promote maritime safety, security, and stewardship for U.S. ports and waterways. Specifically, the Coast Guard inspects containers for compliance with the—

- Federal Hazardous Materials Transportation Law,
- International Safe Containers Act, and
- International Maritime Dangerous Goods Code.

Forms: CG–5577, Intermodal Container Inspection Report; CG–5577A, Intermodal Container Non-Deficiency Inspection Report; CG–5577B, Intermodal Container Targeted Inspection Report.

Respondents: Operators of container facilities.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden is 625 hours annually.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: October 30, 2019.

James D. Roppel,

U.S. Coast Guard, Chief, Office of Information Management.

[FR Doc. 2019–24024 Filed 11–1–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Office of Bombing Prevention Training and Conference Forms

AGENCY: Infrastructure Security Division (ISD), Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: 30-Day notice and request for comments; revision, 1670–0031.

SUMMARY: DHS CISA ISD 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. CISA previously published this ICR for a 60-day public comment period. No comments were received by CISA. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are due by December 4, 2019.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to the OMB Desk Officer, Department of Homeland Security and sent via electronic mail to *dhsdeskofficer@omb.eop.gov.* All submissions must include the words ''Department of Homeland Security'' and the OMB Control Number 1670–0031.

Comments submitted in response to this notice may be made available to the public through relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary

information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Doug DeLancey, 703–235–8207, *dhsobptaskings@HQ.DHS.GOV.*

SUPPLEMENTARY INFORMATION: Under the Homeland Security Presidential Directive-19, DHS was mandated to develop strategies and recommendations on how to deter, prevent, detect, protect against, and respond to IED explosive attacks. DHS thus educates private sector security providers about IED threats, including tactics, techniques, and procedures relevant to their usage, so private sector security providers are knowledgeable about terrorist use of explosives and contribute to a layered security approach.

The Presidential Policy Directive-17 provides guidance to update and gives momentum to our ability to counter threats involving improvised explosive devices. DHS was mandated to deliver standardized IED awareness and familiarization training for federal, state and local responders and public safety personnel. The DHS CISA ISD Office for Bombing Prevention (OBP) must collect various information to effectively deliver this training. Additionally, OBP collects data to provide updated and awareness product information following conferences and other outreach events. OBP describes these collections below.

The purpose of the Volunteer Participant Release of Liability Agreement is to collect necessary information in case an individual who acts as a volunteer role player in support of official OBP training sustains an injury or death during the performance of their supporting role. If legal action is taken, this information can serve as a hold harmless statement/agreement by the Government. In the unlikely event that an injury or death is sustained in the performance of support for training, this information will be used by OBP to protect against legal action by the volunteer or their family. If legal action is taken, this information can serve as a ''hold harmless'' statement/agreement by the Government.

The purpose of the Gratuitous Services Agreement is to establish that no monies, favors or other compensation will be given or received by either party involved in volunteer training. The information from the Gratuitous Services Agreement will be used by OBP in the event that questions arise regarding remuneration or payment for volunteer participation in training events.

The purpose of the OBP Interest Sign-up sheet is to collect an individual's contact information at the training events and conferences. This information is used by OBP in order to follow-up with an individual's questions and to provide the individual with updated or new awareness product information at the conclusion of conference season as well as establish an OBP point of contact for them.

The changes to the collection since the previous OMB approval include: Updating the collection name to better reflect instruments in the collection, adding the collecting of contact information, an increase in burden estimates and costs.

The addition of the Interest Sign-up Sheet has increased the annual burden estimate by 8 hours, which corresponds to an annual cost of $319. It has also increased the annual government burden estimate by 2 hours at an annual cost of $247.

The annual burden cost for the existing collections (*i.e.,* the Volunteer Participant Release of Liability Agreement and the Gratuitous Services Agreement) has increased by $2,204, from $3,894 to $6,098, due to updated hourly compensation rates.

The annual government cost for the existing collections (*i.e.,* the Volunteer Participant Release of Liability Agreement and the Gratuitous Services Agreement) has increased by $11,695, from $6,831 to $18,526, due to updated hourly compensation rates.

This is a revision and renewal of an information collection.

OMB is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Title of Collection: Office of Bombing Prevention Training and Conference Forms.

OMB Control Number: 1670–0031.

Frequency: Annually.

Affected Public: State, Local, Tribal, and Territorial Governments and Private Sector Individuals.

Number of Annualized Respondents: 1,250.

Estimated Time per Respondent: 0.10 hours, 0.02 hours.

Total Annualized Burden Hours: 158 hours.

Total Annualized Respondent Opportunity Cost: $6,416.

Total Annualized Respondent Out-of-Pocket Cost: $0.

Total Annualized Government Cost: $18,773.

Scott Libby,

Deputy Chief Information Officer.

[FR Doc. 2019–24048 Filed 11–1–19; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

Sector Outreach and Programs Online Meeting Registration Tool

AGENCY: Infrastructure Security Division (ISD), Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: 30-Day notice and request for comments; revision, 1670–0019.

SUMMARY: DHS CISA ISD 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. CISA previously published this ICR for a 60-day public comment period. No comments were received by CISA. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are due by December 4, 2019.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to the OMB Desk Officer,

Department of Homeland Security and sent via electronic mail to *dhsdeskofficer@omb.eop.gov.* All submissions must include the words ''Department of Homeland Security'' and the OMB Control Number 1670–0019.

Comments submitted in response to this notice may be made available to the public through relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Auco Ho, 703–603–5205, *sopd_feedback@HQ.DHS.GOV.*

SUPPLEMENTARY INFORMATION: The Critical Infrastructure Protection Act of 2001, 42 U.S.C. 5195c, states that any physical or virtual disruption of the operation of the critical infrastructures of the United States be rare, brief, geographically limited in effect, manageable, and minimally detrimental to the economy, human and government services, and national security of the United States; and that actions necessary to achieve the policy stated be carried out in a public-private partnership involving corporate and non-governmental organizations. On behalf of the DHS, CISA ISD manages the Department's program to protect the Nation's 16 critical infrastructure sectors by implementing the National Infrastructure Protection Plan (NIPP) 2013, Partnering for Critical Infrastructure Security and Resilience. Pursuant to Presidential Policy Directive 21 on Critical Infrastructure Security and Resilience (February 2013), each sector is assigned a Sector-Specific Agency (SSA) to oversee Federal interaction with the array of sector security partners, both public and private. An SSA is responsible for leading a unified public-private sector effort to develop, coordinate, and implement a comprehensive physical, human, and cyber security strategy for its assigned sector. CISA ISD Sector Outreach and Programs (SOP) executes the SSA responsibilities for the six critical infrastructure sectors assigned to ISD: Chemical, Commercial Facilities, Critical Manufacturing, Dams, Emergency Services, and Nuclear Reactors, Materials and Waste (Nuclear).

The mission of SOP is to enhance the resiliency of the Nation by leading the unified public-private sector effort to ensure its assigned critical infrastructure are prepared, more secure, and safer from terrorist attacks, natural disasters, and other incidents. To achieve this mission, SOP leverages the resources and knowledge of its critical infrastructure sectors to develop and apply security initiatives that result in significant, measurable benefits to the Nation.

Each SOP branch builds sustainable partnerships with its public and private sector stakeholders to enable more effective sector coordination, information sharing, and program development and implementation. These partnerships are sustained through the Sector Partnership Model, described in the 2013 NIPP pages 10–12.

Information sharing is a key component of the NIPP Partnership Model, and DHS sponsored conferences are one mechanism for information sharing. To facilitate conference planning and organization, SOP has established an online event registration tool for use by all of its branches. The information collection is voluntary and is used by the SSAs within SOP. The six SSAs within SOP uses this information to register public and private sector stakeholders for meetings hosted by the SSA. The SOP uses the information collected to reserve space at a meeting for the registrant; contact the registrant with a reminder about the event; develop meeting materials for attendees; determine topics of most interest; and efficiently generate attendee and speaker nametags. Additionally, it allows SOP to have a better understanding of the organizations participating in the critical infrastructure protection partnership events. By understanding who is participating, the SSA can identify portions of a sector that are underrepresented, and the SSA could then target that underrepresented sector elements through outreach and awareness initiatives.

The changes to the collection include: Changes to the burden costs, annual government costs, and adding data fields. The registration has been updated to add the following data fields: Attendee ADA Specific Aids or Services Requested (Yes/No), Attendee Organization Company Size, Attendee First Time Attending, Organization Category, Attendee Organization Private Sector Category, Public Sector Category. The annual burden cost for the collection has increased by $175, from $1,627 to $1,802, due to updated compensation rates. The annual government cost for the collection has decreased by $3,269, from $11,615 to $8,347, due to reduced online registration tool annual use fee and a decrease in the cost per registrant from $9.73 to $7.19 per registrant.

This is a revision and renewal of an information collection.

OMB is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Title of Collection: Sector Outreach and Programs Online Meeting Registration Tool.

OMB Control Number: 1670–0019.

Frequency: Annually.

Affected Public: State, Local, Tribal, and Territorial Governments and Private Sector Individuals.

Number of Annualized Respondents: 400.

Estimated Time per Respondent: 0.05 hours.

Total Annualized Burden Hours: 20 hours.

Total Annualized Respondent Opportunity Cost: $1,802.

Total Annualized Respondent Out-of-Pocket Cost: $0.

Total Annualized Government Cost: $8,346.79.

Scott Libby,

Deputy Chief Information Officer.

[FR Doc. 2019–24049 Filed 11–1–19; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket No. TSA–2014–001]

Intent To Request Revision From OMB of One Current Public Collection of Information: TSA Pre✓® Application Program

AGENCY: Transportation Security Administration, DHS.

ACTION: 60-Day notice.

SUMMARY: The Transportation Security Administration (TSA) invites public comment on one currently approved Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0059, abstracted below that we will submit to OMB for a revision in compliance with the Paperwork Reduction Act (PRA). This ICR is being revised to reflect additional enrollment and vendor options in accordance with the TSA Modernization Act, to address TSA's plans to utilize other DHS component services, and to use surveys to determine satisfaction and customer engagement with TSA Pre✓®. The ICR describes the nature of the information collection and its expected burden. The collection involves the voluntary submission of biographic and biometric information that TSA uses to verify identity and conduct a security threat assessment (STA) for the TSA Pre✓® Application Program. The STA compares an applicant's information against criminal history, immigration, intelligence, and regulatory violations databases to determine if the person poses a low risk to transportation or national security and should be eligible for expedited screening through TSA Pre✓® lanes at airports.

DATES: Send your comments by January 3, 2020.

ADDRESSES: Comments may be emailed to *TSAPRA@tsa.dhs.gov* or delivered to the TSA PRA Officer, Information Technology (IT), TSA–11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6011.

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh at the above address, or by telephone (571) 227–2062.

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation will be available at *http://www.reginfo.gov* upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement 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;

(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 using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Consistent with the requirements of Executive Order (E.O.) 13771, Reducing Regulation and Controlling Regulatory Costs, and E.O. 13777, Enforcing the Regulatory Reform Agenda, TSA is also requesting comments on the extent to which this request for information could be modified to reduce the burden on respondents.

Information Collection Requirement

Pursuant to the statutory authorities explained below, the Transportation Security Administration (TSA) has implemented a voluntary enrollment program for individuals to apply for the TSA Pre✓® Application Program. Section 109(a)(3) of the Aviation and Transportation Security Act (ATSA), Public Law 107–71 (115 Stat. 597, 613, Nov. 19, 2001, codified at 49 U.S.C. 114 note) provides TSA with the authority to ''establish requirements to implement trusted programs and use available technologies to expedite security screening of passengers who participate in such programs, thereby allowing security screening personnel to focus on those passengers who should be subject to more extensive screening.'' In addition, TSA has express, statutory authority to establish and collect a fee for any registered traveler program by publication of a notice in the **Federal Register**, as outlined in the Department of Homeland Security Appropriations Act, 2006, Public Law 109–90 (119 Stat. 2064, 2088–89, Oct. 18, 2005).

Under the TSA Pre✓® Application Program, individuals may submit biographic and biometric [1] information directly to TSA that TSA uses to conduct an STA of criminal, immigration, intelligence, and regulatory violation databases. TSA uses the STA results to decide if an individual poses a low risk to transportation or national security. TSA issues approved applicants a known traveler number (KTN) that they may use when making travel reservations. Airline passengers who submit a KTN when making airline reservations are eligible for expedited screening on flights originating from U.S. airports.[2] TSA uses the traveler's KTN and other information during passenger prescreening to verify that the individual traveling matches the information on TSA's list of known travelers and to confirm TSA Pre✓® expedited screening eligibility.

Interested applicants must provide certain minimum required data elements, including, but not limited to, name, date of birth, gender, address, contact information, country of birth, images of identity documents, proof of citizenship or immigration status, and biometrics via a secure interface. TSA uses this information to conduct an STA, make a final eligibility determination for the TSA Pre✓® Application Program, and verify the identities of TSA Pre✓® enrolled and approved individuals when they are traveling.

TSA sends the applicants' fingerprints and associated information to the Federal Bureau of Investigation (FBI) for the purpose of comparing their fingerprints to other fingerprints in the FBI's Next Generation Identification (NGI) system or its successor systems including civil, criminal, and latent fingerprint repositories. The FBI may retain applicants' fingerprints and associated information in NGI after the completion of their application and, while retained, their fingerprints may continue to be compared against other fingerprints submitted to or retained by NGI as part of the FBI's Rap Back program.[3] In retaining applicants' fingerprints, the FBI conducts recurrent vetting of applicants' criminal history until the expiration date of the applicant's STA. TSA also transmits applicants' biometrics for enrollment into the Department of Homeland

[1] Unless otherwise specified, for the purposes of this document, ''biometrics'' refers to fingerprints and/or facial imagery.

[2] Passengers who are eligible for expedited screening typically will receive more limited physical screening; *e.g.,* will be able to leave on their shoes, light outerwear, and belt; to keep their laptop in its case; and to keep their 3–1–1 compliant liquids/gels bag in a carry-on.

[3] The FBI's Rap Back service allows authorized agencies to receive on-going status notifications of any criminal history reported to the FBI after the initial processing and retention of criminal or civil transactions using fingerprint identification.

Security Automated Biometrics Identification System (IDENT) and its successor systems for recurrent vetting of applicants' criminal history, lawful presence, and ties to terrorism.

TSA is revising the collection of information to reflect additional enrollment and vendor options in accordance with the TSA Modernization Act, Division K of the FAA Reauthorization Act of 2018, Public Law 115–254 (132 Stat. 3185; Oct. 5, 2018) at section 1937, codified at 49 U.S.C. 44919. TSA expects to offer additional TSA Pre✓® Application Program enrollment opportunities at airports to reduce the burden on frequent travelers. Enrollment vendors may use commercial sources for the purpose of identity verification, or they may contact issuing sources of identity documents, such as State departments of motor vehicles for the same purpose. This revision also addresses TSA's plans to utilize DHS components' services, provided via U.S. Customs and Border Protection and the Office of Biometric Identity Management, to support TSA's biometric-based identification at the checkpoint and citizenship verification through passport information provided by the Department of State. Lastly, TSA intends to collect information from TSA Pre✓® members after enrollment through surveys to determine satisfaction and customer engagement with TSA Pre✓®.

When the STA is complete, TSA makes a final determination on eligibility for the TSA Pre✓® Application Program and notifies applicants of its decision. Most applicants generally should expect to receive notification from TSA within two to three weeks of the submission of their completed applications. If initially deemed ineligible by TSA, applicants will have an opportunity to correct cases of misidentification or inaccurate criminal records. Applicants must submit a correction of any information they believe to be inaccurate within 60 days of issuance of TSA's letter. If a corrected record is not received by TSA within the specified amount of time, the agency may make a final determination to deny eligibility. Individuals who TSA determines are ineligible for the TSA Pre✓® Application Program will undergo standard screening at airport security checkpoints.

The TSA Pre✓® Application Program enhances aviation security by permitting TSA to better focus its limited security resources on passengers who are unknown to TSA and whose level of risk is undetermined, while also facilitating and improving the commercial aviation travel experience for the public. Travelers who choose not to enroll in this initiative are not subject to any limitations on their travel because of their choice; they will be processed through normal TSA screening before entering the sterile areas of airports. TSA also retains the authority to perform standard or other screening on a random basis on TSA Pre✓® Application Program participants and any other travelers authorized to receive expedited physical screening.

TSA estimates that there will be 1,815,779 new enrollments, 1,245,184 online renewals, and 52,159 in-person renewals (3,113,122 total enrollments) annualized over a three-year period. This estimate is based on current and projected enrollment with TSA's existing program. TSA estimates that there will be 4,211,661 annualized hours based on a three-year projection to include enrollment, renewals, and surveys. TSA estimates an average of 1.8968 hours per applicant to complete the enrollment process, which includes providing biographic and biometric information to TSA (via an enrollment center or pre- or post-enrollment options) and the burden for any records correction for the applicant, if applicable. TSA estimates an average of 0.1666 hours per applicant to complete the on-line renewal process. TSA estimates an average of 0.0833 hours per an estimated 6,310,473 annual survey respondents to include post-enrollment, non-renewal and other TSA Pre✓® surveys.

Dated: October 29, 2019.

Christina A. Walsh,

TSA Paperwork Reduction Act Officer, Information Technology.

[FR Doc. 2019–23971 Filed 11–1–19; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Revision of Agency Information Collection Activity Under OMB Review: TSA infoBoards

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-Day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0065, abstracted below to OMB for review and approval of a revision of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. TSA infoBoards (formerly WebBoards) is an information-sharing environment designed to serve stakeholders in the transportation security community and is used to disseminate mission-critical information. It provides stakeholders with an online portal, which allows authorized users to obtain, post, and exchange information, access common resources, and communicate with similarly situated individuals. Utilizing and inputting information into TSA infoBoards is completely voluntary.

DATES: Send your comments by December 4, 2019. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to *dhsdeskofficer@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh, TSA PRA Officer, Information Technology (IT), TSA–11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6011; telephone (571) 227–2062; email *TSAPRA@tsa.dhs.gov.*

SUPPLEMENTARY INFORMATION: TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on June 20, 2019, 84 FR 28835.

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation will be available at *http://www.reginfo.gov* upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement 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;

(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 using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Consistent with the requirements of Executive Order (E.O.) 13771, Reducing Regulation and Controlling Regulatory Costs, and E.O. 13777, Enforcing the Regulatory Reform Agenda, TSA is also requesting comments on the extent to which this request for information could be modified to reduce the burden on respondents.

Information Collection Requirement

Title: TSA infoBoards.

Type of Request: Revision of a collection.

OMB Control Number: 1652–0065.

Form(s): TSA Forms 1427 and 1430.

Affected Public: Individuals with transportation security responsibilities, such as aircraft operators, airport security coordinators, and international transportation security coordinators.

Abstract: TSA infoBoards was developed by TSA as part of its broad responsibilities and authorities under the Aviation and Transportation Security Act (ATSA), and delegated authority from the Secretary of Homeland Security, for ''security in all modes of transportation . . . including security responsibilities . . . over modes of transportation that are exercised by the Department of Transportation.'' [1] TSA infoBoards is an information-sharing environment designed to serve stakeholders in the transportation security community and is used to disseminate mission-critical information. It is located in a secure online environment and is accessible from the Homeland Security Information Network (HSIN) and TSA (for TSA staff only). Accessing and using TSA infoBoards is completely voluntary; TSA does not require participation.

TSA collects two types of information through TSA infoBoards: (1) User registration information and (2) user's choice of ''communities.'' TSA is revising the collection instrument, TSA Form 1427, TSA infoBoards User Account Request/Renewal, to include an additional instrument, TSA Form 1430, Computer Access Agreement (CAA) External Personnel Only, to correct typographical errors and to update the list of TSA infoBoards names.

Number of Respondents: 5,000 users.

Estimated Annual Burden Hours: An estimated 10,000 hours annually.

Dated: October 29, 2019.

Christina A. Walsh,

TSA Paperwork Reduction Act Officer, Information Technology.

[FR Doc. 2019–23969 Filed 11–1–19; 8:45 am]

BILLING CODE 9110–05–P

[1] *See* Public Law 107–71 (115 Stat. 597, Nov. 19, 2001), codified at 49 U.S.C. 114 (d). The TSA Assistant Secretary's current authorities under ATSA have been delegated to him by the Secretary of Homeland Security. Section 403(2) of the Homeland Security Act (HSA) of 2002, Public Law 107–296 (116 Stat. 2315, Nov. 25, 2002), transferred all functions of TSA, including those of the Secretary of Transportation and the Under Secretary of Transportation of Security related to TSA, to the Secretary of Homeland Security. Pursuant to DHS Delegation Number 7060.2, the Secretary delegated to the Assistant Secretary (then referred to as the Administrator of TSA), subject to the Secretary's guidance and control, the authority vested in the Secretary with respect to TSA, including that in section 403(2) of the HSA.

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2654–19; DHS Docket No. USCIS–2019–0020]

RIN 1615–ZB83

Continuation of Documentation for Beneficiaries of Temporary Protected Status Designations for El Salvador, Haiti, Honduras, Nepal, Nicaragua, and Sudan

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Through this notice, the Department of Homeland Security (DHS) announces actions to ensure its continued compliance with the preliminary injunction orders of the U.S. District Court for the Northern District of California in *Ramos, et al.* v. *Nielsen, et al.,* No. 18–cv–01554 (N.D. Cal. Oct. 3, 2018) (''*Ramos*'') and the U.S. District Court for the Eastern District of New York in *Saget, et al.,* v. *Trump, et al.,* No. 18–cv–1599 (E.D.N.Y. Apr. 11, 2019) (''*Saget*''), and with the order of the U.S. District Court for the Northern District of California to stay proceedings in *Bhattarai* v. *Nielsen,* No. 19–cv–00731 (N.D. Cal. Mar. 12, 2019) (''*Bhattarai*''). Beneficiaries under the Temporary Protected Status (TPS) designations for El Salvador, Honduras, Nepal, Nicaragua, and Sudan will retain their TPS while the preliminary injunction in *Ramos* remains in effect, provided that an alien's TPS is not withdrawn because of individual ineligibility. Beneficiaries under the TPS designation for Haiti will retain their TPS while either of the preliminary injunctions in *Ramos* or *Saget* remain in effect, provided that an alien's TPS is not withdrawn because of individual ineligibility. This notice further provides information on the automatic extension of the validity of TPS-related Employment Authorization Documents (EADs); Notices of Action (Forms I–797); and Arrival/Departure Records (Forms I–94), (collectively ''TPS-related documentation''); for those beneficiaries under the TPS designations for El Salvador, Haiti, Honduras, Nepal, Nicaragua, and Sudan.

DATES: DHS is automatically extending the validity of TPS-related documentation for beneficiaries under the TPS designations for El Salvador, Haiti, Honduras, Nepal, Nicaragua, and Sudan, as specified in this notice. Such TPS-related documentation will remain in effect through January 4, 2021, from the current expiration dates of: January 2, 2020 (for beneficiaries under the TPS designations for El Salvador, Haiti, Nicaragua, and Sudan); January 5, 2020 (for beneficiaries under the TPS designation for Honduras); and March 24, 2020 (for beneficiaries under the TPS designation for Nepal).

FOR FURTHER INFORMATION CONTACT:

- You may contact Maureen Dunn, Chief, Humanitarian Affairs Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, U.S. Department of Homeland Security, by mail at 20 Massachusetts Avenue NW, Washington, DC 20529–2060; or by phone at 800–375–5283.
- For further information on TPS, please visit the USCIS TPS web page at *www.uscis.gov/tps.*
- If you have additional questions about (TPS), please visit *uscis.gov/tools.* Our online virtual assistant, Emma, can answer many of your questions and point you to additional information on our website. If you are unable to find your answers there, you may also call our U.S. Citizenship and Immigration Services (USCIS) Contact Center at 800–375–5283 (TTY 800–767–1833).
- Applicants seeking information about the status of their individual cases may check Case Status Online, available on the USCIS website at *www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).
- Further information will also be available at local USCIS offices upon publication of this notice.

SUPPLEMENTARY INFORMATION:

Table of Abbreviations

CFR—Code of Federal Regulations
DHS—U.S. Department of Homeland Security
EAD—Employment Authorization Document
FNC—Final Nonconfirmation
Form I–765—Application for Employment Authorization
Form I–797—Notice of Action
Form I–821—Application for Temporary Protected Status
Form I–9—Employment Eligibility Verification
Form I–912—Request for Fee Waiver
Form I–94—Arrival/Departure Record
Government—U.S. Government
INA—Immigration and Nationality Act
IER—U.S. Department of Justice Civil Rights Division, Immigrant and Employee Rights Section
SAVE—USCIS Systematic Alien Verification for Entitlements Program
Secretary—Secretary of Homeland Security
TNC—Tentative Nonconfirmation
TPS—Temporary Protected Status
TTY—Text Telephone
USCIS—U.S. Citizenship and Immigration Services

Background on Temporary Protected Status (TPS)

- TPS is a temporary immigration status granted to eligible nationals of a country designated for TPS under the Immigration and Nationality Act (INA) or to eligible persons without nationality who last habitually resided in the designated country.
- During the TPS designation period, TPS beneficiaries are eligible to remain in the United States, may not be removed, and are authorized to obtain EADs so long as they continue to meet the requirements of TPS.
- TPS beneficiaries may also apply for travel authorization as a matter of discretion.
- The granting of TPS does not result in or lead to lawful permanent resident status.
- To qualify for TPS, beneficiaries must meet the eligibility standards at INA section 244(c)(1)–(2), 8 U.S.C. 1254a(c)(1)–(2).
- When the Secretary of Homeland Security (the Secretary) terminates a country's TPS designation, beneficiaries return to one of the following:
  - The same immigration status or category that they maintained before TPS, if any (unless that status or category has since expired or been terminated); or
  - Any other lawfully obtained immigration status or category they received while registered for TPS, as long as it is still valid on the date TPS terminates.

Purpose of This Action

DHS last published notices to ensure its compliance with the *Ramos* preliminary injunction on March 1, 2019, and the *Bhattarai* order to stay proceedings on May 10, 2019. 84 FR 7103; 84 FR 20647. Through this **Federal Register** notice, DHS announces actions to ensure its continued compliance with the *Ramos* and *Saget* preliminary injunction orders and with the order to stay proceedings in *Bhattarai.*

The TPS designations for El Salvador, Nicaragua, and Sudan will remain in effect, as required by the *Ramos* order, so long as the preliminary injunction remains in effect. The TPS designation for Haiti will remain in effect, as required by the preliminary injunction orders in both *Ramos* and *Saget,* so long as either of those preliminary injunctions remain in effect. The TPS designations for Honduras and Nepal will remain in effect, as required by the *Bhattarai* order to stay proceedings, pending final disposition of the Government's appeal of the preliminary injunction order in *Ramos.* Beneficiaries under the TPS designations for El Salvador, Honduras, Nepal, Nicaragua, and Sudan will retain their TPS while the preliminary injunction in *Ramos* remains in effect, and beneficiaries under the TPS designation for Haiti will retain their TPS while the preliminary injunctions in either *Ramos* or *Saget* remain in effect, provided that an alien's TPS status is not withdrawn under INA section 244(c)(3) because of individual ineligibility. *See also* 8 CFR 244.14. DHS will not terminate TPS for any of the affected countries pending final disposition of the *Ramos* appeal, or for Haiti pending both *Ramos* and *Saget* appeals, including through any additional appellate channels in which relief may be sought, or by other orders of the court.

DHS is further announcing it is automatically extending, through January 4, 2021, the validity of certain TPS-related documentation, as specified in this notice, for beneficiaries under the TPS designations for El Salvador, Haiti, Honduras, Nepal, Nicaragua, and Sudan, provided that the affected beneficiaries remain individually eligible for TPS. This notice also provides information explaining DHS's plans to issue subsequent notices that will describe the steps DHS will take to address the status of beneficiaries under the TPS designations for all the affected countries, if continued compliance with the *Ramos* or *Saget* preliminary injunctions or the *Bhattarai* order to stay proceedings becomes necessary.

Automatic Extension of EADs Issued Under the TPS Designations for El Salvador, Haiti, Honduras, Nepal, Nicaragua, and Sudan

Through this **Federal Register** notice, DHS automatically extends the validity of EADs listed in Table 1 below issued to beneficiaries under the TPS designations for El Salvador, Haiti, Honduras, Nepal, Nicaragua, and Sudan. Such individuals may show their automatically-extended EAD to employers to demonstrate they have employment authorization, and may wish also to show employers this **Federal Register** Notice to explain that their TPS-Related Documentation has been extended through January 4, 2021. This Notice explains how TPS beneficiaries, their employers, and benefit-granting agencies may determine which EADs are automatically extended and how this affects the Form I–9, Employment Eligibility Verification, E-Verify, and USCIS Systematic Alien Verification for Entitlements (SAVE) processes. Additionally, a beneficiary under the TPS designation for any of these countries who has applied for a new EAD but who has not yet received his or her new EAD is covered by this automatic extension, provided that the EAD he or she possesses contains one of the expiration dates listed in Table 1 below.

TABLE 1—AFFECTED EADS

If an EAD has a category code of A–12 or C–19 and an expiration date of:	Then the validity of the EAD is extended through:
07/22/2017	01/04/2021
11/02/2017	01/04/2021
01/05/2018	01/04/2021
01/22/2018	01/04/2021
03/09/2018	01/04/2021
06/24/2018	01/04/2021
07/05/2018	01/04/2021
11/02/2018	01/04/2021
01/05/2019	01/04/2021
04/02/2019	01/04/2021
06/24/2019	01/04/2021
07/22/2019	01/04/2021
09/09/2019	01/04/2021
01/02/2020	01/04/2021
01/05/2020	01/04/2021
03/24/2020	01/04/2021

Automatic Extension of Forms I–94 and Forms I–797

Also through this **Federal Register** notice, DHS automatically extends the validity periods of the Forms I–94 and Forms I–797 listed in Table 2 below previously issued to beneficiaries under the TPS designations for El Salvador, Haiti, Honduras, Nepal, Nicaragua, and Sudan. These extensions apply only if

the TPS beneficiary properly filed for re-registration during either the most recent DHS-announced registration period for their country, or any applicable previous DHS-announced re-registration periods for his or her country,[1] or has a re-registration application that remains pending. This notice does not extend the validity periods of Forms I–94 or Forms I–797 for any TPS beneficiary who failed to file for TPS re-registration during one of the applicable previous DHS-announced re-registration periods, or for whom a re-registration request has been finally denied. In addition, the extensions do not apply for any beneficiary from whom TPS has been finally withdrawn.

TABLE 2—AFFECTED FORMS I–94 AND I–797

Country	Beginning date of validity:	End date of validity:	Validity of Forms I–94 and I–797 extended through:
El Salvador	Sept. 10, 2016	Mar. 9, 2018	01/04/2021
	Mar. 10, 2018	Sept. 9, 2019	01/04/2021
Haiti	Jan. 23, 2016	Jul. 22, 2017	01/04/2021
	Jul. 23, 2017	Jan. 22, 2018	01/04/2021
	Jan. 23, 2018	July 22, 2019	01/04/2021
Honduras	July 6, 2016	Jan. 5, 2018	01/04/2021
	Jan. 6, 2018	July 5, 2018	01/04/2021
	July 6, 2018	Jan. 5, 2020	01/04/2021
Nepal	Dec. 25, 2016	June 24, 2018	01/04/2021
	June 25, 2018	June 24, 2019	01/04/2021
Nicaragua	July 6, 2016	Jan. 5, 2018	01/04/2021
	Jan. 6, 2018	Jan. 5, 2019	01/04/2021
Sudan	May 3, 2016	Nov. 2, 2017	01/04/2021
	Nov. 3, 2017	Nov. 2, 2018	01/04/2021

Application Procedures

Current beneficiaries under the TPS designations for El Salvador, Haiti, Honduras, Nepal, Nicaragua, and Sudan do not need to pay a fee or file any application, including Application for Employment Authorization (Form I–765), to maintain their TPS benefits through January 4, 2021, provided that they have properly re-registered for TPS during either the most recent DHS-announced registration period for their country, or any applicable previous re-registration period described in Footnote 1, above.

TPS beneficiaries who have failed to re-register properly for TPS during any of these re-registration periods may still file an Application for Temporary Protected Status (Form I–821), but must demonstrate ''good cause'' for failing to re-register on time, as required by law. *See* INA section 244(c)(3)(C) (TPS beneficiary's failure to register without good cause in form and manner specified by DHS is ground for TPS withdrawal); 8 CFR 244.17(b) and Form I–821 instructions.

Any currently eligible beneficiary who does not presently have a pending EAD application under the TPS designations for El Salvador, Haiti, Honduras, Nepal, Nicaragua, or Sudan may file Form I–765 with appropriate fee.

Possible Future Action

In order to comply with statutory requirements for TPS while the district courts' orders or any superseding court order concerning the beneficiaries under the TPS designations for El Salvador, Haiti, Honduras, Nepal, Nicaragua, and Sudan are pending, DHS may require these beneficiaries to re-register and announce the re-registration procedures in a future **Federal Register** notice. *See* section 244(c)(3)(C) of the INA; 8 CFR 244.17.

The Government has appealed both the *Ramos* and *Saget* preliminary injunctions. Should the Government prevail in its challenge to the *Ramos* preliminary injunction, the Secretary's determination to terminate TPS for Honduras, Nepal, Nicaragua, and Sudan will take effect no earlier than 120 days from the issuance of any appellate mandate to the district court. The Secretary's determination to terminate TPS for El Salvador will take effect no earlier than 365 days from the issuance of any appellate mandate to the *Ramos* district court. DHS provides this additional time for El Salvador TPS beneficiaries in part because there are almost 100,000 more such beneficiaries than in the combined TPS beneficiary populations of all the other five countries covered by this notice.[2] The additional period of 245 days beyond 120 days permits an orderly transition for beneficiaries of TPS from El Salvador as they return to their homeland. If the Government prevails in its appeals, DHS will also continue to monitor the circumstances of the affected beneficiaries under the other five TPS country designations covered by this notice. *See* INA 244(d)(3).

TPS for beneficiaries under Haiti's designation may continue pursuant to the *Saget* preliminary injunction. However, should the Government prevail in its challenges to both the *Ramos* preliminary injunction and the

[1] El Salvador: July 8—Sept. 6, 2016 (corresponding to an end validity date of Mar. 9, 2018) or Jan. 18–Mar. 19, 2018 (corresponding to an end validity date of Sept. 9, 2019); Haiti: Aug. 25—Oct. 26, 2015 (corresponding to an end validity date of July 22, 2017), May 24—July 24, 2017 (corresponding to an end validity date of Jan. 22, 2018), or Jan. 18—Mar. 19, 2018 (corresponding to an end validity date of July 22, 2019); Honduras: May 16—July 15, 2016 (corresponding to an end validity date of Jan. 5, 2018); Dec. 15, 2017—Feb. 13, 2018 (corresponding to an end date of July 5, 2018) or June 5—Aug. 6, 2018 (corresponding to an end validity date of Jan. 5, 2020); Nepal: Oct. 26—Dec. 27, 2016 (corresponding to an end validity date of June 24, 2018) or May 22—July 23, 2018 (corresponding to an end validity date of June 24, 2019); Nicaragua: May 16—July 15, 2016 (corresponding to an end validity date of Jan. 5, 2018) or Dec. 15, 2017—Feb. 13, 2018 (corresponding to an end validity date of Jan. 5, 2019); Sudan: Jan. 25—Mar. 25, 2016 (corresponding to an end validity date of Nov. 2, 2017) or Oct. 11, 2017—Dec. 11, 2017 (corresponding to an end validity date of Nov. 2, 2018).

[2] As reported to Congress on May 1, 2019 in the DHS Annual Congressional Report on TPS, there were 251,445 TPS beneficiaries from El Salvador at the end of 2018. In contrast, there were 56,114 beneficiaries from Haiti, 80,570 beneficiaries from Honduras, 14,594 beneficiaries from Nepal, 4,508 beneficiaries from Nicaragua, and 805 beneficiaries from Sudan. As reported, there are 94,854 more beneficiaries of TPS from El Salvador than the combined total of all other countries whose terminations are currently enjoined by court order.

Saget preliminary injunction, the Secretary's determination to terminate TPS for Haiti will take effect no earlier than 120 days from the issuance of the later of the two appellate mandates to the District Court. To the extent that a **Federal Register** notice has automatically extended TPS-related documentation beyond 120 days from the issuance of any appellate mandate to the District Court, DHS reserves the right to issue a subsequent **Federal Register** notice announcing an expiration date for the documentation that corresponds to the last day of the 120-day period. Should the Government move to vacate the *Bhattarai* order to stay proceedings, TPS will remain in effect for Honduras and Nepal for at least 180 days following an order of the District Court vacating the stay in proceedings.

Additional Notes

Nothing in this notice affects DHS's ongoing authority to determine on a case-by-case basis whether a TPS beneficiary continues to meet the eligibility requirements for TPS described in section 244(c) of the INA and the implementing regulations in part 244 of Title 8 of the Code of Federal Regulations.

Notice of Compliance With the ''Order Enjoining the Implementation and Enforcement of Determinations to Terminate the TPS Designations for El Salvador, Haiti, Nicaragua, and Sudan'' in *Ramos,* the ''Order Enjoining the Implementation of Enforcement of Determination to Terminate the TPS Designation of Haiti'' in *Saget,* and the ''Order to Stay Proceedings and Agreement to Stay the Determinations to Terminate the TPS Designations for Honduras and Nepal'' in *Bhattarai*

The previously-announced determinations to terminate the existing designations of TPS for El Salvador, Nicaragua, and Sudan [3] will not be implemented or enforced unless and until the district court's order in *Ramos* is reversed and that reversal becomes final. The previously-announced determination to terminate the existing designation of TPS for Haiti will not be implemented or enforced unless and until the district court's orders in *Ramos* and *Saget* are reversed and those reversals become final.[4] As required by the order to stay proceedings in *Bhattarai,* DHS will not implement or enforce the previously-announced determinations to terminate the existing TPS designations for Honduras and Nepal [5] unless and until the district court's order in *Ramos* enjoining implementation and enforcement of the determinations to terminate the TPS designations for El Salvador, Haiti, Nicaragua, and Sudan is reversed and that reversal becomes final for some or all of the affected countries, or by other order of the court. Any termination of TPS-related documentation for beneficiaries under the TPS designations for Haiti, Honduras, Nicaragua, Nepal, and Sudan will go into effect no earlier than 120 days, and no earlier than 365 days for beneficiaries under the TPS designation for El Salvador, following the issuance of any mandate to the district court, as described in the ''Possible Future Action'' section of this **Federal Register** notice.[6]

In further compliance with the orders, DHS is publishing this notice automatically extending the validity of the TPS-related documentation specified in the Supplementary Information section of this notice through January 4, 2021, for eligible beneficiaries under the TPS designations for El Salvador, Haiti, Honduras, Nepal, Nicaragua, and Sudan. DHS will continue to issue notices that will automatically extend TPS-related documentation for all affected beneficiaries under the TPS designations for El Salvador, Honduras, Nicaragua, Nepal, and Sudan, so long as the *Ramos* preliminary injunction and *Bhattarai* order to stay proceedings remain in place; for Haiti so long as either the *Ramos* or *Saget* preliminary injunctions remain in place; or by other order of the court. However, should compliance with the *Ramos, Bhattarai,* and/or *Saget* court orders remain necessary, DHS may announce periodic re-registration procedures for eligible TPS beneficiaries in accordance with the INA and DHS regulations. DHS further continues its commitment to a transition period, as described above.

All TPS beneficiaries must continue to maintain their TPS eligibility by meeting the requirements for TPS in INA section 244(c) and 8 CFR part 244. DHS will continue to adjudicate any pending TPS re-registration and pending late initial applications for affected beneficiaries under the TPS designations for El Salvador, Haiti, Honduras, Nicaragua, Nepal, and Sudan, and continue to make appropriate individual TPS withdrawal decisions in accordance with existing procedures if an alien no longer maintains TPS eligibility. DHS will take appropriate steps to continue its compliance with the orders, and with all statutory requirements.

Dated: October 29, 2019.

Kevin K. McAleenan,

Acting Secretary.

Approved Forms To Demonstrate Continuation of Lawful Status and TPS-Related Employment Authorization

- This **Federal Register** notice November 4, 2019

○ Through operation of this notice, certain TPS-related documentation, including EADs, of affected beneficiaries under the TPS designations for El Salvador, Haiti, Honduras, Nepal, Nicaragua, and Sudan are automatically extended through January 4, 2021.

○ A beneficiary granted TPS under the designation for El Salvador, Haiti, Honduras, Nepal, Nicaragua, or Sudan may show his or her EAD that has been automatically extended to his or her employer to demonstrate identity and continued TPS-related employment eligibility to meet Employment Eligibility Verification (Form I–9) requirements. A beneficiary granted TPS under a designation for one of these countries may also wish to show an employer this **Federal Register** notice, which explains that his or her EAD has been automatically extended.

○ Alternatively, such a TPS beneficiary may choose to show other acceptable documents that are evidence of identity and employment eligibility as described in the instructions to Form I–9.

○ Finally, such a TPS beneficiary may show a copy of this **Federal Register** notice, along with his or her EAD that has been automatically extended, or Form I–94, or Form I–797, as evidence of his or her lawful status, to law enforcement, Federal, state, and local government agencies, and private entities.

[3] *See* Termination of the Designation of El Salvador for Temporary Protected Status, 83 FR 2654 (Jan. 18, 2018); Termination of the Designation of Nicaragua for Temporary Protected Status, 82 FR 59636 (Dec. 15, 2017); Termination of the Designation of Sudan for Temporary Protected Status, 82 FR 47228 (Oct. 11, 2017).

[4] *See* Termination of the Designation of Haiti for Temporary Protected Status, 83 FR 2648 (Jan. 18, 2018).

[5] *See* Termination of the Designation of Honduras for Temporary Protected Status, 83 FR 26074 (June 5, 2018); Termination of the Designation of Nepal for Temporary Protected Status, 83 FR 23705 (May 22, 2018).

[6] An additional provision in the *Bhattarai* Order to Stay Proceedings states that if the Government moves to vacate that Order, TPS will remain in effect for Honduras and Nepal for at least 180 days following an order of the District Court vacating its stay of proceedings order.

- Employment Authorization Document (EAD)

Am I eligible to receive an automatic extension of my current EAD using this Federal Register notice?

Yes. Provided that you currently have a TPS-related EAD with the specified expiration dates below, this notice automatically extends your EAD as stated in Table 3 below.

TABLE 3—AFFECTED EADS

If your EAD has category code of A–12 or C–19 and an expiration date of:	Then this Federal Register notice extends your EAD through:
07/22/2017	01/04/2021
11/02/2017	01/04/2021
01/05/2018	01/04/2021
01/22/2018	01/04/2021
03/09/2018	01/04/2021
06/24/2018	01/04/2021
07/05/2018	01/04/2021
11/02/2018	01/04/2021
01/05/2019	01/04/2021
04/02/2019	01/04/2021
06/24/2019	01/04/2021
07/22/2019	01/04/2021
09/09/2019	01/04/2021
01/02/2020	01/04/2021
01/05/2020	01/04/2021
03/24/2020	01/04/2021

When hired, what documentation may I show to my employer as evidence of employment authorization and identity when completing Form I–9?

You can find the Lists of Acceptable Documents on the third page of Form I–9 as well as the Acceptable Documents web page at *www.uscis.gov/i-9-central/acceptable-documents.* Employers must complete Form I–9 to verify the identity and employment authorization of all new employees. Within 3 days of hire, employees must present acceptable documents to their employers as evidence of identity and employment authorization to satisfy Form I–9 requirements.

You may present any document from List A (which provides evidence of both your identity and employment authorization) or one document from List B (which provides evidence of your identity) together with one document from List C (which provides evidence of your employment authorization), or you may present an acceptable receipt as described in the Form I–9 instructions. Employers may not reject a document based on a future expiration date. You can find additional information about Form I–9 on the I–9 Central web page at *www.uscis.gov/I-9Central.*

An EAD is an acceptable document under List A. See the section ''How do my employer and I complete Form I–9 using my automatically extended employment authorization for a new job?'' of this **Federal Register** notice for further information. If you present your EAD with one of the expiration dates specified below, you may also provide your employer with a copy of this **Federal Register** notice, which explains that your EAD has been automatically extended for a temporary period of time, through January 4, 2021, as follows:

TABLE 4—AFFECTED EADS AND FORM I–9

You may show your EAD to complete Form I–9 if your EAD has category code of A–12 or C–19 and bears an expiration date of:	Enter this date in Section 1 of Form I–9:	Your employer must reverify your employment authorization by:
07/22/2017	01/04/2021	01/05/2021
11/02/2017	01/04/2021	01/05/2021
01/05/2018	01/04/2021	01/05/2021
01/22/2018	01/04/2021	01/05/2021
03/09/2018	01/04/2021	01/05/2021
06/24/2018	01/04/2021	01/05/2021
07/05/2018	01/04/2021	01/05/2021
11/02/2018	01/04/2021	01/05/2021
01/05/2019	01/04/2021	01/05/2021
04/02/2019	01/04/2021	01/05/2021
06/24/2019	01/04/2021	01/05/2021
07/22/2019	01/04/2021	01/05/2021
09/09/2019	01/04/2021	01/05/2021
01/02/2020	01/04/2021	01/05/2021
01/05/2020	01/04/2021	01/05/2021
03/24/2020	01/04/2021	01/05/2021

What documentation may I present to my employer for Form I–9 if I am already employed but my current TPS-related EAD is set to expire?

Even though your EAD has been automatically extended, your employer is required by law to ask you to verify your continued employment authorization, and you will need to present your employer with evidence that you are still authorized to work. Once presented, your employer should correct the EAD expiration date in Section 2 of Form I–9. *See* the section, ''What corrections should my current employer make to Form I–9 if my employment authorization has been automatically extended?'' of this **Federal Register** notice for further information. You may show this **Federal Register** notice to your employer to explain what to do for Form I–9 and to show that your EAD has been automatically extended through January 4 2021, as indicated in the above chart. Your employer may need to re-inspect your automatically extended EAD to check the Card Expires date and Category code if your employer did not keep a copy of your EAD when you initially presented it.

The last day of the automatic extension for your EAD is January 4, 2021. Before you start work on January 5, 2021, your employer is required by law to reverify your employment authorization in Section 3 of Form I–9. At that time, you must present any document from List A or any document from List C on Form I–9, Lists of Acceptable Documents, or an acceptable List A or List C receipt described in the Form I–9 instructions to reverify employment authorization.

If your original Form I–9 was a previous version, your employer must complete Section 3 of the current version of Form I–9, and attach it to your previously completed Form I–9. Your employer can check the I–9 Central web page at *www.uscis.gov/I-9Central* for the most current version of Form I–9.

Your employer may not specify which List A or List C document you must present and cannot reject an acceptable receipt.

Can I obtain a new EAD?

Yes, if you apply and remain eligible for TPS, you can obtain a new EAD. However, you do not need to apply for a new EAD in order to benefit from this automatic extension. If you are a beneficiary under the TPS designations for El Salvador, Haiti, Honduras, Nepal, Nicaragua, or Sudan and want to obtain a new EAD valid through January 4, 2021, then you must file Form I–765 and pay the associated fee. If you do not want a new EAD, you do not have to file Form I–765 or pay the Form I–765 fee. If you do not want to request a new EAD now, you may file Form I–765 at a later date and pay the fee, provided that you still have TPS or a pending TPS application. You may file the application for a new EAD either before or after your current EAD has expired.

If you are unable to pay the application fee and/or biometric services fee, you may complete a Request for Fee Waiver (Form I–912) consistent with applicable form instructions. For more information on the application forms and fees for TPS, please visit the USCIS TPS web page at *www.uscis.gov/tps.* Fees for Form I–821, Form I–765, and biometric services are also described in 8 CFR 103.7(b)(1)(i).

If you have a Form I–821 and/or Form I–765 application that is still pending as of January 2, 2020 (for beneficiaries under the TPS designations for El Salvador, Haiti, Nicaragua, or Sudan); January 5, 2020 (for beneficiaries under the TPS designation for Honduras); or March 24, 2020 (for beneficiaries under the TPS designation for Nepal); then you should not file either application again. If your pending Form I–821 is approved, you will be issued Forms I–797 and I–94 through January 4, 2021. Similarly, if you have a pending TPS-related Form I–765 that is approved, your new EAD will be valid through January 4, 2021.

Your TPS itself continues as long as the preliminary injunction impacting your country's TPS designation remains in effect and in accordance with any relevant future **Federal Register** notices that DHS may issue respecting your country's TPS designation, or your TPS is finally withdrawn for individual ineligibility under INA, section 244(c), or the applicable TPS designation is terminated as discussed in the ''Possible Future Action'' section of this **Federal Register** notice.

Can my employer require that I provide any other documentation to prove my status, such as proof of my citizenship from El Salvador, Haiti, Honduras, Nepal, Nicaragua, or Sudan?

No. When completing Form I–9, including reverifying employment authorization, employers must accept any documentation that appears on the Form I–9 Lists of Acceptable Documents that reasonably appears to be genuine and that relates to you, or an acceptable List A, List B, or List C receipt. Employers need not reverify List B identity documents. Employers may not request documentation that does not appear on the Lists of Acceptable Documents. Therefore, employers may not request proof of citizenship or proof of re-registration for TPS when completing Form I–9 for new hires or reverifying the employment authorization of current employees. If presented with an EAD that has been automatically extended, employers should accept such a document as a valid List A document, so long as the EAD reasonably appears to be genuine and relates to the employee. Refer to the ''Note to Employees'' section of this **Federal Register** notice for important information about your rights if your employer rejects lawful documentation, requires additional documentation, or otherwise discriminates against you based on your citizenship or immigration status, or your national origin.

How do my employer and I complete Form I–9 using my automatically extended employment authorization for a new job?

See the chart in the question above ''When hired, what documentation may I show to my employer as evidence of employment authorization and identity when completing Form I–9?'' to determine if your EAD has been automatically extended.

For Section 1, you should:

a. Check ''An alien authorized to work until'' and enter January 4, 2021, as the expiration date indicated in the chart; and

b. Enter your USCIS number or A–Number where indicated (your EAD or other document from DHS will have your USCIS number or A–Number printed on it; the USCIS number is the same as your A–Number without the A prefix).

For Section 2, your employer should also use the chart in the question above ''When hired, what documentation may I show to my employer as evidence of employment authorization and identity when completing Form I–9?'' to determine if your EAD has been automatically extended. If it has been automatically extended, the employer should:

a. Write in the document title;

b. Enter the issuing authority;

c. Enter either the employee's A–Number or USCIS number from Section 1 in the Document Number field on Form I–9; and

d. Write January 4, 2021, as the expiration date indicated in the chart.

Before the start of work on January 5, 2021, employers are required by law to reverify the employee's employment authorization in Section 3 of Form I–9. If your original Form I–9 was a previous version, your employer must complete Section 3 of the current version of Form I–9 and attach it to your previously completed Form I–9. Your employer can check the I–9 Central web page at *www.uscis.gov/I-9Central* for the most current version of Form I–9.

What corrections should my current employer make to Form I–9 if my employment authorization has been automatically extended?

If you presented a TPS-related EAD that was valid when you first started your job and your EAD has now been automatically extended, your employer may need to re-inspect your current EAD if they do not have a copy of the EAD on file. See the chart in the question above ''When hired, what documentation may I show to my employer as evidence of employment authorization and identity when completing Form I–9?'' to determine if your EAD has been automatically extended. If your employer determines that your EAD has been automatically extended, your employer should correct Section 2 of your previously completed Form I–9 as follows:

a. Write EAD EXT and January 4, 2021, as the last day of the automatic extension in the Additional Information field; and

b. Initial and date the correction.

Note: This is not considered a reverification. Employers do not need to complete Section 3 until either this notice's automatic extension of EADs has ended or the employee presents a new document to show continued employment authorization, whichever is sooner. By January 5, 2021, when the employee's automatically extended EAD

has expired, employers are required by law to reverify the employee's employment authorization in Section 3. If your original Form I–9 was a previous version, your employer must complete Section 3 of the current version of Form I–9 and attach it to your previously completed Form I–9. Your employer can check the I–9 Central web page at *www.uscis.gov/I-9Central* for the most current version of Form I–9.

If I am an employer enrolled in E-Verify, how do I verify a new employee whose EAD has been automatically extended?

Employers may create a case in E-Verify for a new employee by providing the employee's A–Number or USCIS number from Form I–9 in the Document Number field in E-Verify. Employers should enter January 4, 2021 for the document expiration date.

If I am an employer enrolled in E-Verify, what do I do when I receive a ''Work Authorization Documents Expiration'' alert for an automatically extended EAD?

If you have an employee who provided a TPS-related EAD with an expiration date that has been automatically extended by this **Federal Register** notice, you should dismiss the ''Work Authorization Documents Expiring'' case alert. Before this employee starts work on January 5, 2021, as appropriate, you must reverify his or her employment authorization in Section 3 of Form I–9. Employers should not use E-Verify for reverification.

Note to All Employers

Employers are reminded that the laws requiring proper employment eligibility verification and prohibiting unfair immigration-related employment practices remain in full force. This **Federal Register** notice does not supersede or in any way limit applicable employment verification rules and policy guidance, including those rules setting forth reverification requirements. For general questions about the employment eligibility verification process, employers may call USCIS at 888–464–4218 (TTY 877–875–6028) or email USCIS at *I-9Central@dhs.gov.* USCIS accepts calls and emails in English, Spanish, and many other languages. For questions about avoiding discrimination during the employment eligibility verification process (Form I–9 and E-Verify), employers may call the U.S. Department of Justice's Civil Rights Division, Immigrant and Employee Rights Section (IER) Employer Hotline at 800–255–8155 (TTY 800–237–2515). IER offers language interpretation in numerous languages. Employers may also email IER at *IER@usdoj.gov.*

Note to Employees

For general questions about the employment eligibility verification process, employees may call USCIS at 888–897–7781 (TTY 877–875–6028) or email USCIS at *I-9Central@dhs.gov.* USCIS accepts calls in English, Spanish, and many other languages. Employees or applicants may also call the IER Worker Hotline at 800–255–7688 (TTY 800–237–2515) for information regarding employment discrimination based upon citizenship, immigration status, or national origin, including discrimination related to Form I–9 and E-Verify. The IER Worker Hotline provides language interpretation in numerous languages.

To comply with the law, employers must accept any document or combination of documents from the Lists of Acceptable Documents if the documentation reasonably appears to be genuine and to relate to the employee, or an acceptable List A, List B, or List C receipt as described in the Form I–9 instructions. Employers may not require extra or additional documentation beyond what is required for Form I–9 completion. Further, employers participating in E-Verify who receive an E-Verify case result of ''Tentative Nonconfirmation'' (TNC) must promptly inform employees of the TNC and give such employees an opportunity to contest the TNC. A TNC case result means that the information entered into E-Verify from an employee's Form I–9 differs from records available to DHS.

Employers may not terminate, suspend, delay training, withhold pay, lower pay, or take any adverse action against an employee because of the TNC while the case is still pending with E-Verify. A ''Final Nonconfirmation'' (FNC) case result is received when E-Verify cannot verify an employee's employment eligibility. An employer may terminate employment based on a case result of FNC. Work-authorized employees who receive an FNC may call USCIS for assistance at 888–897–7781 (TTY 877–875–6028). For more information about E-Verify-related discrimination or to report an employer for discrimination in the E-Verify process based on citizenship, immigration status, or national origin, contact IER's Worker Hotline at 800–255–7688 (TTY 800–237–2515). Additional information about proper nondiscriminatory Form I–9 and E-Verify procedures is available on the IER website at *www.justice.gov/ier* and on the USCIS and E-Verify websites at *www.uscis.gov/i-9-central* and *www.e-verify.gov.*

Note Regarding Federal, State, and Local Government Agencies (Such as Departments of Motor Vehicles)

While Federal Government agencies must follow the guidelines laid out by the Federal Government, state and local government agencies establish their own rules and guidelines when granting certain benefits. Each state may have different laws, requirements, and determinations about what documents you need to provide to prove eligibility for certain benefits. Whether you are applying for a federal, state, or local government benefit, you may need to provide the government agency with documents that show you are a TPS beneficiary, show you are authorized to work based on TPS or other status, and/or that may be used by DHS to determine whether you have TPS or other immigration status. Examples of such documents are:

- Your current EAD;
- Your automatically extended EAD with a copy of this **Federal Register** notice, providing an automatic extension of your currently expired or expiring EAD;
- A copy of your Form I–94 or Form I–797 that has been automatically extended by this notice and a copy of this notice;
- Any other relevant DHS-issued document that indicates your immigration status or authorization to be in the United States, or that may be used by DHS to determine whether you have such status or authorization to remain in the United States.

Check with the government agency regarding which document(s) the agency will accept.

Some benefit-granting agencies use the USCIS Systematic Alien Verification for Entitlements Program (SAVE) program to confirm the current immigration status of applicants for public benefits. While SAVE can verify when an alien has TPS, each agency's procedures govern whether they will accept a particular document, such as an EAD or an I–94. If an agency accepts the type of TPS-related document you are presenting, such as an EAD or I–94, the agency should accept your automatically extended TPS-related document. You should:

a. Present the agency with a copy of this **Federal Register** notice showing the extension of TPS-related documentation, in addition to your most recent TPS-related document with your A–Number or I–94 number;

b. Explain that SAVE will be able to verify the continuation of your TPS using this information; and

c. Ask the agency to initiate a SAVE query with your information and follow through with additional verification steps, if necessary, to get a final SAVE response showing the validity of your TPS.

You can also ask the agency to look for SAVE notices or contact SAVE if they have any questions about your immigration status or automatic extension of TPS-related documentation. In most cases, SAVE provides an automated electronic response to benefit-granting agencies within seconds, but, occasionally, verification can be delayed. You can check the status of your SAVE verification by using CaseCheck at *save.uscis.gov/casecheck/,* then by clicking the ''Check Your Case'' button. CaseCheck is a free service that lets you follow the progress of your SAVE verification case using your date of birth and one immigration identifier number. If an agency has denied your application based solely or in part on a SAVE response, the agency must offer you the opportunity to appeal the decision in accordance with the agency's procedures. If the agency has received and acted upon or will act upon a SAVE verification case and you do not believe the response is correct, you may make an InfoPass appointment for an in-person interview at a local USCIS office. Detailed information on how to make corrections or update your immigration record, make an appointment, or submit a written request to correct records under the Freedom of Information Act can be found on the SAVE website at *www.uscis.gov/save.*

[FR Doc. 2019–24047 Filed 11–1–19; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7015–N–09]

60-Day Notice of Proposed Information Collection: Public Housing Capital Fund Program

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, PIH, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 3, 2020.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Arlette Mussington, Office of Policy, Programs and Legislative Initiatives, PIH, Department of Housing and Urban Development, 451 7th Street SW, (L'Enfant Plaza, Room 2206), Washington, DC 20410; telephone 202–402–4109, (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the Federal Information Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Mussington.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Public Housing Capital Fund Program.

OMB Approval Number: 2577–0157.

Type of Request: Revision of a currently approved collection.

Form Numbers: HUD Form 50075.1, HUD–5084, HUD–5087, HUD–51000, HUD–51001, HUD–51002, HUD–51003, HUD–5104, HUD–51915, HUD–51915–A, HUD–51971–I–II, HUD–52396, HUD–52427, HUD–52482, HUD–52483–A, HUD–52484, HUD–52485, HUD–52651–A, HUD–52829, HUD–52830, HUD–52833, HUD–52845, HUD–52846, HUD–52847, HUD–52849, HUD–53001, HUD–53015, HUD–5370, HUD–5370EZ, HUD–5370C, HUD–5372, HUD–5378, HUD–5460, HUD–52828, 50071, 5370–C1, 5370–C2.

Description of the need for the information and proposed use: Each year Congress appropriates funds to approximately 3,015 Public Housing Authorities (PHAs) for modernization, development, financing, and management improvements. The funds are allocated based on a complex formula. The forms in this collection are used to appropriately disburse and utilize the funds provided to PHAs. Additionally, these forms provide the information necessary to approve a financing transaction in addition to any Capital Fund Financing transactions. Respondents include the approximately 3,015 PHA receiving Capital Funds and any other PHAs wishing to pursue financing.

This proposed information collection has been revised to include the following changes below:

1. HUD has removed all of the hours for the annual submission of form HUD–50075.2 and reduced the hours for HUD–50075.1. HUD is now collecting that information electronically thru the Energy Performance Information Center (EPIC) system. These hours were transferred to OMB No. 2577–0274 Energy Performance Information Center (EPIC). HUD will continue to use the HUD–50075.1 for the Capital Fund set aside grant programs, Lead Based Paint, Emergency Safety and Security, and Emergency and Disaster. Only those hours remain in 2577–0157.1. As a result, the burden hours were decreased 9,260 hours

2. Due to conversion of Public Housing to the Section 8 thru the Rental Assistance Demonstration (RAD) Program, the number of PHAs receiving Capital Funds has been reduced from 3,100 to 3,015. This has reduced the number of hours by 3,774.

3. The total reduction in burden hours are 13,034.

Respondents (*i.e. affected public*): Public Housing Authorities.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
HUD–5084	3,015	1	3,015	1.5	4,522.50	$34	$153,765
HUD–5087	50	1	50	3	150	56	8,400
HUD–50071	10	1	10	0.5	5	56	280
HUD–50075.1	300	1	300	2.2	660	34	204,600

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
HUD–51000	590	1	590	1	590	34	20,600
HUD–51001	2,550	12	30,600	3.5	107,100	34	3,641,000
HUD–51002	1,600	5	8,000	1	8,000	34	272,000
HUD–51003	500	2	1,000	1.5	1,500	34	51,000
HUD–51004	500	2	1,000	2.5	2,500	34	85,000
HUD–51915 and HUD–51915–A	2,630	1	2,630	3	7,890	34	268,260
HUD–51971–I, II	80	1	80	1.5	120	34	4,080
HUD–52396	96	1	96	2	192	34	6,528
HUD–52427	88	1	88	0.5	44	34	1,496
HUD–52482	40	1	40	2	80	34	2,720
HUD–52483–A	40	1	40	2	80	34	2,720
HUD–52484	532	4	2,128	10	21,280	34	723,520
HUD–52485	40	1	40	1	40	34	1,360
HUD–52651–A	40	1	40	2.5	100	34	3,400
HUD–52829	25	1	25	40	1000	56	56,000
HUD–52830	25	1	25	16	400	56	22,400
HUD–52833	3,015	1	3,015	13	30,915	34	1,332,630
HUD–52836	10	1	10	0.5		56	280
HUD–52845	25	1	25	8	200	56	11,200
HUD–52846	25	1	25	16	400	56	22,400
HUD–52847	25	1	25	8	200	56	11,200
HUD–52849	25	1	25	1	25	56	1,400
HUD–53001	3,015	1	3,015	2.5	7,537	34	256,275
HUD–53015	40	1	40	3	120	34	4,080
HUD–5370, 5370EZ	2,694	1	2,694	1	2,694	34	91,596
HUD–5370C	2,694	1	2,694	1	2,694	34	91,596
HUD–5372	590	1	590	1	590	34	20,060
HUD–5378	158	24	3,792	0.25	948	34	32,232
HUD–5460	40	1	40	1	40	34	1,360
Public Housing Information Center Certification of Accuracy	3,015	1	3,015	2	6,030.00	34	186,000
HUD–52828—Physical Needs Assessment form	3,015	1	3,015	15.4	46,431	56	2,600,136
Broadband Feasibility determination	3,015	1	3,015	10	30,150	56	1,688,400
Totals					293,593.00		11,716,694

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(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;

(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 those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: October 7, 2019.

Merrie Nichols-Dixon,

Director, Office of Policy, Programs and Legislative Initiatives.

[FR Doc. 2019–23963 Filed 11–1–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7016–N–02]

60-Day Notice of Proposed Information Collection: Application for Distressed Cities Technical Assistance NOFA

AGENCY: Office of Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: The Department of Housing and Urban Development (HUD) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comments from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 3, 2020.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Anna P. Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–5534 (this is not a toll-free number) or by email at *Anna.P.Guido@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410–5000; email Anna P. Guido at *Anna.P.Guido@hud.gov* or telephone 202–402–5535 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the

proposed collection of information described in Section A.

A. Overview of Information Collection

Title of Information Collection: Application for Distressed Cities Technical Assistance NOFA.

OMB Approval Number: New Collection.

Type of Request: New Collection.

Form Number: SF–424, SF–LLL, HUD–2880.

Description of the need for the information and proposed use: Application information is needed to determine the competition winner, *i.e.,* the technical assistance provider best able to help distressed communities adopt effective, efficient, and sustainable financial management practices, build capacity for financial management, economic revitalization, affordable housing, and disaster recovery, and improve knowledge of federal development programs.

Members of Affected Public: Organizations.

Estimated Number of Respondents: 10.

Estimated Time per Response: 44 hours.

Frequency of Response: 1.

Estimated Total Annual Burden Hours: 440 hours.

Estimated Total Annual Cost: The total estimated cost is $11,000.

Legal Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Respondents (i.e., affected public): Organizations.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Pre-Award							
Narrative Response	10	1	10	40.00	400.00	$25.00	$10,000.00
HUD SF–424	10	1	10	2.00	20.00	25.00	500.00
HUD–2880	10	1	10	2.00	20.00	25.00	500.00
SF–LLL*	.....	.....	.....	.....	.....	.....	.....
Total	10	.....	.....	44.00	440.00	25.00	11,000.00

* Per OMB, Standard Form should be listed, but the burden does not need to be included as part of the collection. Annualized Cost @$25/hr: $62,361.00.

B. Solicitation of Public Comment

This notice solicits comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(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;

(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 those who are to respond, including the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: October 7, 2019.

Seth Appleton,

Assistant Secretary for Policy Development and Research.

[FR Doc. 2019–23962 Filed 11–1–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7020–N–02]

Notice of Proposed Information Collection: Comment Request; Ginnie Mae Multiclass Securities Program Documents (Forms and Electronic Data Submissions); Notice of Proposed Information Collection: Comment Request

AGENCY: Office of the President of Government National Mortgage Association (Ginnie Mae), HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due: January 3, 2020.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Anna Guido, QDAM, Information Reports Management Officer, Department of Housing and Urban Development, 451 7th Street SW, L'Enfant Plaza Building, Room 4186, Washington, DC 20410; *email: Anna.P.Guido@hud.gov;* telephone (202) 708–2384. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

FOR FURTHER INFORMATION CONTACT: Shalei Choi, Ginnie Mae, 451 7th Street SW, Room B–133, Washington, DC 20410; email—*Shalei.Choi@hud.gov;* telephone—(202) 475–7820; (this is not a toll-free number); the Ginnie Mae website at *www.ginniemae.gov* for other available information.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, as amended).

This Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (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 collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Ginnie Mae Multiclass Securities Program Documents. (Forms and Electronic Data Submissions).

OMB Control Number, if applicable: 2503–0030.

Description of the need for the information and proposed use: This information collection is required in connection with the operation of the Ginnie Mae Multiclass Securities program. Ginnie Mae's authority to guarantee multiclass instruments is contained in 306(g)(1) of the National Housing Act (''NHA'') (12 U.S.C. 1721(g)(1)), which authorizes Ginnie Mae to guarantee ''securities * * * based on or backed by a trust or pool composed of mortgages. * * *'' Multiclass securities are backed by Ginnie Mae securities, which are backed by government insured or guaranteed mortgages. Ginnie Mae's authority to operate a Multiclass Securities program is recognized in Section 3004 of the Omnibus Budget Reconciliation Act of 1993 (''OBRA''), which amended 306(g)(3) of the NHA (12 U.S.C. 1271(g)(3)) to provide Ginnie Mae with greater flexibility for the Multiclass Securities program regarding fee structure, contracting, industry consultation, and program implementation. Congress annually sets Ginnie Mae's commitment authority to guarantee mortgage-backed (''MBS'') pursuant to 306(G)(2) of the NHA (12 U.S.C. 1271(g)(2)). Since the multiclass are backed by Ginnie Mae Single Class MBS, Ginnie Mae has already guaranteed the collateral for the multiclass instruments.

The Ginnie Mae Multiclass Securities Program consists of Ginnie Mae Real Estate Mortgage Investment Conduit (''REMIC'') securities, Stripped Mortgage-Backed Securities (''SMBS''), and Platinum securities. The Multiclass Securities program provides an important adjunct to Ginnie Mae's secondary mortgage market activities, allowing the private sector to combine and restructure cash flows from Ginnie Mae Single Class MBS into securities that meet unique investor requirements in connection with yield, maturity, and call-option protection. The intent of the Multiclass Securities program is to increase liquidity in the secondary mortgage market and to attract new sources of capital for federally insured or guaranteed loans. Under this program, Ginnie Mae guarantees, with the full faith and credit of the United States, the timely payment of principal and interest on Ginnie Mae REMIC, SMBS and Platinum securities.

Agency form numbers, if applicable: Not applicable.

Members of affected public: For-profit business (mortgage companies, thrifts, savings & loans, etc.).

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response:

Information collection	Number of respondents	Frequency response	Responses per annum	Burden hour per response	Annual burden hrs	Hourly cost per response	Annual cost
REMIC Securities							
Pricing Letter	18	10	180	0.5	90	$43	$3,870
Structured Term Sheet	18	10	180	3	540	43	23,220
Trust (REMIC) Agreement	18	10	180	1	180	43	7,740
Trust Opinion	18	10	180	4	720	43	30,960
MX Trust Agreement	18	10	180	0.16	28.8	43	1,238
MX Trust Opinion	18	10	180	4	720	43	30,960
RR Certificate	18	10	180	0.08	14.4	43	619
Sponsor Agreement	18	10	180	0.05	9	43	387
Table of Contents	18	10	180	0.33	59.4	43	2,554
Issuance Statement	18	10	180	0.5	90	43	3,870
Tax Opinion	18	10	180	4	720	43	30,960
Transfer Affidavit	18	10	180	0.08	14.4	43	619
Supplemental Statement	18	0.25	4.5	1	4.5	43	194
Final Data Statements (attached to closing letter)	18	10	180	32	5,760	43	247,680
Accountants' Closing Letter	18	10	180	8	1,440	43	61,920
Accountants' OSC Letter	18	10	180	8	1,440	43	61,920
Structuring Data	18	10	180	8	1,440	43	61,920
Financial Statements	18	10	180	1	180	43	7,740
Principal and Interest Factor File Specifications	18	10	180	16	2,880	43	123,840
Distribution Dates and Statement	18	10	180	0.42	75.6	43	3,251
Term Sheet	18	10	180	2	360	43	15,480
New Issue File Layout	18	10	180	4	720	43	30,960
Flow of Funds	18	10	180	0.16	28.8	43	1,238
Trustee Receipt	18	10	180	2	360	43	15,480
Subtotal			4,144.50		17,874.90		768,621
Platinum Securities							
Deposit Agreement	19	10	190	1	190	43	8,170
MBS Schedule	19	10	190	0.16	30.4	43	1,307
New Issue File Layout	19	10	190	4	760	43	32,680

Information collection	Number of respondents	Frequency response	Responses per annum	Burden hour per response	Annual burden hrs	Hourly cost per response	Annual cost
Principal and Interest Factor File Specifications	19	10	190	16	3,040	43	130,720
Subtotal			760		4,020.40		172,877
Total Annual Responses			4,904.50				
Total Burden Hours					21,895.30		
Total Cost							941,498

Status of the proposed information collection: Reinstatement, with change, of a previously approved collection.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35 as amended.

Dated: September 26, 2019.

John Getchis,

Senior Vice President, Office of Capital Markets, Government National Mortgage Association.

[FR Doc. 2019–23961 Filed 11–1–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[XXX.LLAZG02000.71220000.KD0000. LVTFA0958340;AZA3116]

Notice of Availability of Record of Decision for the Ray Land Exchange Final Supplemental Environmental Impact Statement/Proposed Plan Amendment, Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended, and Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM), Gila District, announces the availability of the Record of Decision (ROD) for the Final Supplemental Environmental Impact Statement (EIS)/Plan Amendment for the Ray Land Exchange located in Pinal and Gila counties in southeastern Arizona.

DATES: Simultaneous to the publication of the Record of Decision, the BLM will publish in a local newspaper a Notice of Decision for the land exchange, which will initiate a 45-day protest period per 43 CFR 2200.7–1(b). Protests must be received by December 19, 2019.

ADDRESSES: Copies of the ROD are available upon request from the Project Manager, Michael Werner, address: One North Central Avenue, Suite 800, Phoenix, AZ 85004–4427, or on the BLM ePlanning project website at *https://go.usa.gov/xEnKR.* Copies of the ROD are available for public inspection at the BLM Arizona State Office, and the Kingman and Tucson Field Offices.

Protests related to the proposed land exchange, as described in the Notice of Decision, must be submitted in writing to the State Director, Attn: Project Manager—Ray Land Exchange Protest, U.S. Bureau of Land Management, Arizona State Office, One North Central Avenue, Suite 800, Phoenix, Arizona 85004–4427.

FOR FURTHER INFORMATION CONTACT: Project Manager Michael Werner, telephone: 602–417–9561; email: *mwerner@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The BLM Arizona State Director signed the ROD on October 24, 2019 to amend the Phoenix, Lower Sonoran and Safford Resource Management Plans (RMPs) to change the land tenure status of all the Selected Lands originally considered to be exchanged (10,976 acres) from ''retention'' to ''available for disposal'' (approximately 9,906 acres in the Phoenix RMP (1989); approximately 637 acres in the Lower Sonoran RMP (2012); and approximately 433 acres in the Safford RMP (1992, 1994)). The ROD also approved a land exchange between ASARCO LLC and the BLM for 9,339 acres (7,196 acres of full estate and 2,143 acres of subsurface mineral estate only) of BLM-administered public lands for acquisition by ASARCO in exchange for approximately 7,298 acres (6,938 of full estate, and 360 of surface estate only) of private land. Implementation of the ROD occurs only upon expiration of the 45-day protest period for the land exchange (43 CFR 2201.7–1) and the resolution of any protests.

Before including your address, phone number, email address, or other personal identifying information in your appeal, you should be aware that your entire protest—including your personal identifying information—may be made publicly available at any time. While you can ask us in your protest to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Under the approved Ray Land Exchange with ASARCO LLC, the BLM acquires 7,298 acres of land in Pinal and Mohave Counties, consolidating checkerboard land ownership in those areas and improving access to existing public lands for hunting and other types of recreation. In exchange, the BLM transfers to ASARCO 9,339 acres of surface and subsurface estate near ASARCO's Ray Mine Complex and Copper Butte properties in Pinal and Gila Counties, near Kearny. Since the public lands appraised at a higher value than the private lands, to equalize the value, the BLM will accept a cash payment of the maximum allowable amount (25 percent of the value of the federal lands) from ASARCO. Approximately 1,637 acres of surface and sub-surface estate originally selected by ASARCO will remain under BLM ownership.

The Ray Land Exchange Supplemental EIS/Plan Amendment was developed with stakeholder dialogue throughout the planning process. The BLM was not required to conduct scoping for the Supplemental EIS. However, the agency has conducted public outreach activities to inform the public and answer questions regarding

the proposed land exchange. The efforts included conducting four public meetings, updating the mailing list for the project, contacting mailing list persons via postcard and newsletter, providing a detailed project website, and interviewing key stakeholders to present details of the land exchange and answer questions. The BLM also put the Draft Supplemental EIS out for a 90-day public comment period and responsed to comments in the Final Supplemental EIS. The Final Supplemental EIS/Proposed Plan Amendment was published on July 12, 2019.

The Ray Land Exchange Final Supplemental EIS/Proposed Plan Amendment required a 30-day protest period after publication of the Final Supplemental EIS. During the 30-day protest period, the BLM Director received one protest letter. Three of the protest points in the protest letter were remanded back to the State Director for resolution. These three protest points are resolved in the ROD. In addition, the protest letter contained comments on the Final Supplemental EIS. The majority of these comments were previously addressed in the Final Supplemental EIS as response to comments on the Draft Supplemental EIS and responses are captured in Appendix J of the Final Supplemental EIS. Some comments required additional explanation and clarification in the ROD. Neither the protests nor the comments required changes to the Final Supplemental EIS.

The BLM prepared an errata sheet to the Final Supplemental EIS to make some clarifications on BLM's subsurface estate acreage. No comments regarding potential inconsistencies with State and local plans, programs, and policies were received from the Governor's Office during the Governor's Consistency Review process.

(Authority: 40 CFR 1506.6)

Raymond Suazo,

Arizona State Director.

[FR Doc. 2019–24056 Filed 11–1–19; 8:45 am]

BILLING CODE 4130–32–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1181]

Certain Lithium-Ion Battery Cells, Battery Modules, Battery Packs, Components Thereof, and Products Containing the Same; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on September 26, 2019, under section 337 of the Tariff Act of 1930, as amended, on behalf of LG Chem, Ltd. of the Republic of Korea; LG Chem Michigan Inc. of Holland, Michigan; and Toray Industries, Inc. of Japan. A supplement was filed on September 27, 2019. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain lithium-ion battery cells, battery modules, battery packs, components thereof (including battery separators and powderous electrode active material), and vehicles containing same by reason of infringement of certain claims of U.S. Patent No. 7,662,517 (''the '517 patent''); U.S. Patent No. 7,638,241 (''the '241 patent''); U.S. Patent No. 7,709,152 (''the '152 patent''); and U.S. Patent No. 7,771,877 (''the '877 patent''). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute. The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *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*.

FOR FURTHER INFORMATION CONTACT: Katherine Hiner, Office of Docket Services, U.S. International Trade Commission, telephone (202) 205–1802.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2019).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on October 28, 2019, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1, 2, 5–15, and 18 of the '517 patent; claims 1–5, 9–12, 14–31, and 33–36 of the '241 patent; claims 1–13 and 16–20 of the '152 patent; and claims 1–7, 18, 20–21, and 23–26 of the '877 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is ''lithium-ion battery cells, battery modules, battery packs, components thereof (including battery separators and powderous electrode active material), and vehicles containing the same'';

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

LG Chem, Ltd., LG Twin Towers, 128 Yeoui-daero, Yeongdeungpo-gu, Seoul 07336, Republic of Korea

LG Chem Michigan Inc., 1 LG Way, Holland, MI 49423

Toray Industries, Inc., Nihonbashi Mitsui Tower, 1–1, Nihonbashi-Muromachi, 2-chome, Chuo-ku, Tokyo 103–0022, Japan

(b) The respondents are the following entities alleged to be in violation of section 337, and is/are the parties upon which the complaint is to be served:

SK Innovation Co., Ltd., 26 Jongno-gu, Jongno-gu, Seoul 03188, Republic of Korea

SK Battery America, Inc., 201 17th Street NW, Suite 1700, Atlanta, GA 30363

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission,

shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not participate as a party in this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: October 29, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–23989 Filed 11–1–19; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1125]

Certain Height-Adjustable Desk Platforms and Components Thereof; Commission Determination Not To Review an Initial Determination Granting in Part a Motion for Summary Determination; Schedule for Filing Written Submissions on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined not to review the presiding administrative law judge's (''ALJ'') initial determination (''ID'') (Order No. 33) granting in part a summary determination on violation of section 337 by certain non-participating respondents in the above-captioned investigation. The Commission is requesting briefing from the parties, interested government agencies, and interested persons on the issues of remedy, the public interest, and bonding.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3427. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's Electronic Docket Information System (''EDIS'') (*https://edis.usitc.gov*). Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205–1810.

SUPPLEMENTARY INFORMATION: On July 30, 2018, the Commission instituted this investigation based on a complaint and supplements thereto filed on behalf of Varidesk LLC of Coppell, Texas (''Varidesk''). 83 FR 36621 (July 30, 2018). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain height-adjustable desk platforms and components thereof by reason of infringement of one or more claims of U.S. Patent Nos. 9,113,703 (''the '703 patent''); 9,277,809 (''the '809 patent''); 9,554,644 (''the '644 patent''); and 9,924,793 (''the '793 patent''). *Id.* The complaint further alleges that an industry in the United States exists as required by section 337. *Id.*

The Commission's notice of investigation named thirty-one respondents: (1) Albeit LLC of San Francisco, California (''Albeit''); (2) ATC Supply LLC of Plainfield, Illinois (''ATC Supply''); (3) Shenzhen Atc Network Scienology CO., LTD. of Guangdong, China (''Shenzhen ATC''); (4) Best Choice Products of Ontario, California (''Best Choice''); (5) Huizhou Chang He Home Supplies Co., Ltd. of Guangdong, China (''Chang He''); (6) Dakota Trading, Inc. of Emerson, New Jersey (''Dakota''); (7) Designa Inc. of Guangdong, China (''Designa''); (8) Designa Group, Inc. of El Dorado Hills, California (''Designa Group''); (9) Eureka LLC of El Dorado Hills, California (''Eureka''); (10) LaMountain International Group LLC of Elk Grove, California (''LaMountain''); (11) Amazon Import Inc. of El Monte, California (''Amazon Imports''); (12) Hangzhou Grandix Electronics Co., Ltd. of Zhejiang, China (''Grandix''); (13) Ningbo GYL International Trading Co., Ltd. of Zhejiang, China (''Ningbo GYL''); (14) Knape & Vogt Manufacturing Co. of Grand Rapids, Michigan (''Knape & Vogt''); (15) JV Products Inc. of Milpitas, California (''JV Products''); (16) Vanson Distributing, Inc. of Milpitas, California (''Vanson Distributing''); (17) Vanson Group, Inc. of Milpitas, California (''Vanson Group''); (18) S.P. Richards Co. DBA Lorell of Smyrna, Georgia (''Lorell''); (19) Nantong Jon Ergonomic Office Co., Ltd. of Jiangsu, China (''Nanotong Jon''); (20) Jiangsu Omni Industrial Co., Ltd. of Jiangsu, China (''Jiangsu Omni''); (21) OmniMax USA, LLC of Anna, Texas (''OmniMax USA''); (22) Haining Orizeal Import and Export Co., Ltd. of Zhejiang, China (''Haining Orizeal''); (23) Qidong Vision Mounts Manufacturing Co., Ltd. of Jiangsu, China (''Vision Mounts''); (24) Hangzhou KeXiang Keji Youxiangongsi of Hangzhou, China (''Hangzhou KeXiang''); (25) Smugdesk, LLC of La Puente, California (''Smugdesk''); (26) Venditio Group, LLC of Elkton, Florida (''Venditio''); (27) Versa Products Inc. of Los Angeles, California (''Versa''); (28) Victor Technology, LLC of Bolingbrook, Illinois (''Victor''); (29) CKnapp Sales, Inc. DBA Vivo of Goodfield, Illinois (''Vivo''); (30) Wuhu Xingdian Industrial Co., Ltd. of Anhui, China (''Wuhu Xingdian''); and (31) Wuppessen, Inc. of Ontario, California (''Wuppessen''). *Id.* The Office of Unfair Import Investigations (''OUII'') was also named as a party in this investigation. *Id.*

During the course of the investigation, Varidesk settled with the following respondents: Venditio, Jiangsu Omni, OmniMax USA, Knape & Vogt, Wuppessen, Victor, Versa, Designa, Designa Group, Eureka, Chang He, Vision Mounts, Vivo, Nanotong Jon, Best Choice, Grandix, Hangzhou KeXiang, Lorell, and Dakota. Order No. 7, *unreviewed,* Notice (Sept. 18, 2018); Order No. 11, *unreviewed,* Notice (Sept. 25, 2018); Order No. 12, *unreviewed,* Notice (Oct. 4, 2018); Order No. 13,

unreviewed, Notice (Oct. 4, 2018); Order No. 16, *unreviewed,* Notice (Nov. 9, 2018); Order No. 18, *unreviewed,* Notice (Nov. 29, 2018); Order No. 20, *unreviewed,* Notice (Feb. 21, 2019); Order No. 23, *unreviewed,* Notice (Mar. 12, 2019); Order No. 25, *unreviewed,* Notice (Apr. 5, 2019); Order No. 31, *unreviewed,* Notice (May 16, 2019). In addition, the investigation terminated as to LaMountain based on a consent order stipulation. Order No. 15, *unreviewed,* Notice (Oct. 22, 2018). The investigation has also previously terminated as to certain claims of each asserted patent. Order No. 30, *unreviewed,* Notice (May 13, 2019).

On April 11, 2019, Varidesk moved for summary determination of a violation of section 337 as to the remaining eleven respondents, who were served with a copy of the complaint, but have not filed a response or participated in the investigation. On April 24, 2019, Varidesk filed a supplement to the motion. The remaining respondents (collectively, ''the Non-Participating Respondents'') are (1) Albeit, (2) ATC Supply, (3) Shenzhen ATC, (4) Amazon Imports, (5) Ningbo GYL, (6) JV Products, (7) Vanson Distributing, (8) Vanson Group, (9) Haining Orizeal, (10) Smugdesk, and (11) Wuhu Xingdian. On April 26, 2019, OUII filed a response supporting Varidesk's motion in substantial part.

On September 13, 2019, the ALJ issued Order No. 33, the subject ID, and his Recommended Determination (''RD'') on remedy and bonding. The ID grants the motion in part. Specifically, the ALJ found, *inter alia,* (1) that Varidesk established the importation requirement as to each Non-Participating Respondent, except for Haining Orizeal; (2) that Varidesk established infringement as to all accused products and all remaining asserted claims (claims 1–2, 4, and 10–11 of the '703 patent; claims 11, 16, 18, and 22–26 of the '809 patent; claims 1, 4–5, 11–12, 26, and 33–36 of the '644 patent; and claims 20–21 and 40–50 of the '793 patent); and (3) that Varidesk satisfied the domestic industry requirement for each asserted patents. In addition, the ALJ recommended that the Commission issue a general exclusion order and impose a 100 percent bond during the period of Presidential review. The ALJ also recommended the Commission not issue cease and desist orders directed to the Non-Participating Respondents.

Having examined the record in this investigation, including the ID, the Commission has determined not to review the ID. Thus, the Commission has determined that there is a violation of section 337 as to Albeit, ATC Supply, Shenzhen ATC, Amazon Imports, Ningbo GYL, JV Products, Vanson Distributing, Vanson Group, Smugdesk, and Wuhu Xingdian, but not as to Haining Orizeal.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue a cease and desist order that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843, Comm'n Op. at 7–10 (December 1994). In addition, if a party seeks issuance of any cease and desist orders, the written submissions should address that request in the context of recent Commission opinions, including those in *Certain Arrowheads with Deploying Blades and Components Thereof and Packaging Therefor,* Inv. No. 337–TA–977, Comm'n Op. (Apr. 28, 2017) and *Certain Electric Skin Care Devices, Brushes and Chargers Therefor, and Kits Containing the Same,* Inv. No. 337–TA–959, Comm'n Op. (Feb. 13, 2017). Specifically, if Complainant seeks a cease and desist order against a respondent, the written submissions should respond to the following requests:

1. Please identify with citations to the record any information regarding commercially significant inventory in the United States as to each respondent against whom a cease and desist order is sought. If Complainant also relies on other significant domestic operations that could undercut the remedy provided by an exclusion order, identify with citations to the record such information as to each respondent against whom a cease and desist order is sought.

2. In relation to the infringing products, please identify any information in the record, including allegations in the pleadings, that addresses the existence of any domestic inventory, any domestic operations, or any sales-related activity directed at the United States for each respondent against whom a cease and desist order is sought.

3. Please discuss any other basis upon which the Commission could enter a cease and desist order.

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005. 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding.

Complainant and OUII are requested to submit proposed remedial orders for the Commission's consideration. Complainant is also requested to state the date that the patents expire and the HTSUS numbers under which the accused products are imported. Complainant is further requested to supply the names of known importers of the products at issue in this investigation. The written submissions and proposed remedial orders must be filed no later than close of business on November 13, 2019. Reply submissions must be filed no later than the close of business on November 20, 2019. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to Commission Rule 210.4(f), CFR 210.4(f). Submissions should refer to the investigation number (''Inv. No. 337–TA–1125'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/secretary/documents/handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted-non-confidential version of the document must also be filed simultaneously with any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes (all contract personnel will sign appropriate nondisclosure agreements). All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: October 29, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–23988 Filed 11–1–19; 8:45 am]

BILLING CODE 7020–02–P

LEGAL SERVICES CORPORATION

Notice of Intent To Award—Grant Awards for the Delivery of Civil Legal Services to Eligible Low-Income Clients Beginning January 1, 2020

AGENCY: Legal Services Corporation.

ACTION: Announcement of the Legal Services Corporation's intent to make FY2020 Grant Awards.

SUMMARY: The Legal Services Corporation (LSC) hereby announces its intention to award grants to provide effective and efficient delivery of high-quality civil legal services to eligible low-income clients, starting January 1, 2020.

DATES: All comments and recommendations must be received on or before the close of business on December 4, 2019.

ADDRESSES: Grant Awards, Legal Services Corporation; 3333 K Street NW, Third Floor, Washington, DC 20007.

FOR FURTHER INFORMATION CONTACT: Judith Lee, Grants Program Analyst, Office of Program Performance, at (202) 295–1518 or *leej@lsc.gov.*

SUPPLEMENTARY INFORMATION: Under LSC's Notice Of Funds Available published on March 12, 2019 (84 FR 8904) and LSC's Grant Renewal application process beginning on May 3, 2019, LSC intends to award funds to organizations that provide civil legal services in the indicated service areas. Applicants for each service area are listed below. The grant award amounts below are estimates based on the FY2019 grant awards to each service area. The funding estimates may change based on the final FY2020 appropriation.

LSC will post all updates and changes to this notice at *https://www.lsc.gov/grants-grantee-resources.* Interested parties are asked to visit *https://www.lsc.gov/grants-grantee-resources* regularly for updates on the LSC grants process.

Name of applicant organization	State	Service area	Estimated annualized 2020 funding
Alaska Legal Services Corporation	AK	AK–1	$871,350
Alaska Legal Services Corporation	AK	NAK–1	601,148
Legal Services Alabama	AL	AL–4	6,525,818
Legal Aid of Arkansas	AR	AR–6	1,478,027
Center for Arkansas Legal Services	AR	AR–7	2,350,621
American Samoa Legal Aid	AS	AS–1	265,156
DNA-Peoples Legal Services	AZ	AZ–2	468,529
Community Legal Services	AZ	AZ–3	5,463,795
Southern Arizona Legal Aid	AZ	AZ–5	2,310,084
Community Legal Services	AZ	MAZ	251,318
DNA-Peoples Legal Services	AZ	NAZ–5	2,900,567
Southern Arizona Legal Aid	AZ	NAZ–6	708,525
California Indian Legal Services	CA	CA–1	14,237
Inland Counties Legal Services	CA	CA–12	5,000,021
Legal Aid Society of San Diego	CA	CA–14	2,975,476
Community Legal Aid SoCal	CA	CA–19	4,015,508
Greater Bakersfield Legal Assistance	CA	CA–2	1,266,090
Central California Legal Services	CA	CA–26	3,202,966
Legal Services of Northern California	CA	CA–27	4,128,982
Bay Area Legal Aid	CA	CA–28	4,268,687
Legal Aid Foundation of Los Angeles	CA	CA–29	6,104,238
Neighborhood Legal Services of Los Angeles County	CA	CA–30	4,201,601
California Rural Legal Assistance	CA	CA–31	4,750,556
California Rural Legal Assistance	CA	MCA	3,086,473
California Indian Legal Services	CA	NCA–1	982,050

Name of applicant organization	State	Service area	Estimated annualized 2020 funding
Colorado Legal Services	CO	CO–6	4,448,393
Colorado Legal Services	CO	MCO	255,631
Colorado Legal Services	CO	NCO–1	106,750
Statewide Legal Services of Connecticut	CT	CT–1	2,716,257
Pine Tree Legal Assistance	CT	NCT–1	17,403
Neighborhood Legal Services Program of DC	DC	DC–1	916,281
Legal Services Corporation of Delaware	DE	DE–1	1,042,692
Maryland Legal Aid	DE	MDE	15,841
Legal Services of North Florida	FL	FL–13	1,721,338
Three Rivers Legal Services	FL	FL–14	2,437,893
Community Legal Services of Mid-Florida	FL	FL–15	5,235,443
Bay Area Legal Services	FL	FL–16	3,836,668
Florida Rural Legal Services	FL	FL–17	4,072,439
Coast to Coast Legal Aid of South Florida	FL	FL–18	2,391,396
Legal Services of Greater Miami	FL	FL–5	3,731,958
Florida Rural Legal Services	FL	MFL	659,448
Atlanta Legal Aid Society	GA	GA–1	3,743,270
Georgia Legal Services Program	GA	GA–2	8,580,422
Georgia Legal Services Program	GA	MGA	327,681
Micronesian Legal Services	GU	GU–1	298,825
Legal Aid Society of Hawaii	HI	HI–1	1,263,345
Legal Aid Society of Hawaii	HI	NHI–1	254,624
Iowa Legal Aid	IA	IA–3	2,326,575
Iowa Legal Aid	IA	MIA	396,217
Idaho Legal Aid Services	ID	ID–1	1,499,653
Idaho Legal Aid Services	ID	MID	303,482
Idaho Legal Aid Services	ID	NID–1	72,216
Land of Lincoln Legal Assistance Foundation	IL	IL–3	2,870,858
Legal Aid Chicago	IL	IL–6	6,026,217
Prairie State Legal Services	IL	IL–7	3,882,914
Legal Aid Chicago	IL	MIL	305,309
Indiana Legal Services	IN	IN–5	7,038,234
Indiana Legal Services	IN	MIN	224,364
Kansas Legal Services	KS	KS–1	2,804,900
Legal Aid of the Bluegrass	KY	KY–10	1,610,521
Legal Aid Society	KY	KY–2	1,274,926
Appalachian Research and Defense Fund of Kentucky	KY	KY–5	1,783,602
Kentucky Legal Aid	KY	KY–9	1,311,205
Acadiana Legal Service Corporation	LA	LA–15	3,717,027
Southeast Louisiana Legal Services Corporation	LA	LA–13	3,595,109
Community Legal Aid	MA	MA–10	1,592,032
Volunteer Lawyers Project of the Boston Bar Assoc	MA	MA–11	2,204,486
South Coastal Counties Legal Services	MA	MA–12	925,556
Northeast Legal Aid	MA	MA–4	978,344
Legal Aid Bureau	MD	MD–1	4,517,677
Legal Aid Bureau	MD	MMD	60,141
Pine Tree Legal Assistance	ME	ME–1	1,104,539
Pine Tree Legal Assistance	ME	MMX–1	309,844
Pine Tree Legal Assistance	ME	NME–1	71,645
Michigan Advocacy Program	MI	MI–12	1,797,936
Lakeshore Legal Aid	MI	MI–13	4,705,305
Legal Services of Eastern Michigan	MI	MI–14	1,712,356
Legal Aid of Western Michigan	MI	MI–15	2,029,464
Legal Services of Northern Michigan	MI	MI–9	852,171
Michigan Advocacy Program	MI	MMI	387,617
Michigan Indian Legal Services	MI	NMI–1	182,981
Southern Minnesota Regional Legal Services	MN	MMN	342,254
Legal Aid Service of Northeastern Minnesota	MN	MN–1	422,289
Legal Services of Northwest Minnesota Corporation	MN	MN–4	369,489
Southern Minnesota Regional Legal Services	MN	MN–5	1,576,495
Central Minnesota Legal Services	MN	MN–6	1,603,087
Anishinabe Legal Services	MN	NMN–1	265,642
Legal Aid of Western Missouri	MO	MMO	236,989
Legal Aid of Western Missouri	MO	MO–3	1,974,831
Legal Services of Eastern Missouri	MO	MO–4	2,064,536
Mid-Missouri Legal Services Corporation	MO	MO–5	463,716
Legal Services of Southern Missouri	MO	MO–7	1,893,084
Micronesian Legal Services	MP	MP–1	1,498,617
Mississippi Center for Legal Services	MS	MS–10	2,839,558
North Mississippi Rural Legal Services	MS	MS–9	1,759,221
Mississippi Center for Legal Services	MS	NMS–1	92,398
Montana Legal Services Association	MT	MMT	129,054

Name of applicant organization	State	Service area	Estimated annualized 2020 funding
Montana Legal Services Association	MT	MT–1	936,063
Montana Legal Services Association	MT	NMT–1	176,990
Legal Aid of North Carolina	NC	MNC	461,988
Legal Aid of North Carolina	NC	NC–5	11,802,933
Legal Aid of North Carolina	NC	NNC–1	242,593
Southern Minnesota Regional Legal Services	ND	MND	145,187
Legal Services of North Dakota	ND	MND	145,187
Legal Services of North Dakota	ND	ND–3	482,339
Legal Services of North Dakota	ND	NND–3	299,424
Legal Aid of Nebraska	NE	MNE	271,334
Legal Aid of Nebraska	NE	NE–4	1,403,429
Legal Aid of Nebraska	NE	NNE–1	36,743
Legal Advice & Referral Center	NH	NH–1	803,572
South Jersey Legal Services	NJ	MNJ	85,080
Legal Services of Northwest Jersey	NJ	NJ–15	491,774
Central Jersey Legal Services	NJ	NJ–17	1,338,877
Northeast New Jersey Legal Services Corporation	NJ	NJ–18	1,992,228
South Jersey Legal Services	NJ	NJ–20	2,425,172
Essex-Newark Legal Services Project	NJ	NJ–8	1,024,705
New Mexico Legal Aid	NM	MNM	116,955
DNA-Peoples Legal Services	NM	NM–1	248,825
New Mexico Legal Aid	NM	NM–5	2,983,204
DNA-Peoples Legal Services	NM	NNM–2	25,254
New Mexico Legal Aid	NM	NNM–4	516,474
Nevada Legal Services	NV	NNV–1	147,808
Nevada Legal Services	NV	NV–1	3,201,980
Legal Aid Society of Mid-New York	NY	MNY	297,340
Legal Services of the Hudson Valley	NY	NY–20	1,879,422
Legal Aid Society of Northeastern New York	NY	NY–21	1,395,529
Legal Aid Society of Mid-New York	NY	NY–22	1,790,944
Legal Assistance of Western New York	NY	NY–23	1,892,831
Neighborhood Legal Services	NY	NY–24	1,427,284
Nassau/Suffolk Law Services Committee	NY	NY–7	1,480,182
Legal Services NYC	NY	NY–9	12,528,874
Legal Aid of Western Ohio	OH	MOH	274,582
Legal Aid Society of Greater Cincinnati	OH	OH–18	1,771,694
Community Legal Aid Services	OH	OH–20	2,057,869
The Legal Aid Society of Cleveland	OH	OH–21	2,504,027
Legal Aid of Western Ohio	OH	OH–23	2,934,227
Ohio State Legal Services	OH	OH–24	3,652,724
Legal Aid Services of Oklahoma	OK	MOK	169,151
Oklahoma Indian Legal Services	OK	NOK–1	910,133
Legal Aid Services of Oklahoma	OK	OK–3	4,864,598
Legal Aid Services of Oregon	OR	MOR	541,632
Legal Aid Services of Oregon	OR	NOR–1	205,195
Legal Aid Services of Oregon	OR	OR–6	3,942,866
Philadelphia Legal Assistance Center	PA	MPA	217,368
Philadelphia Legal Assistance Center	PA	PA–1	3,242,685
Southwestern Pennsylvania Legal Services	PA	PA–11	429,938
Legal Aid of Southeastern Pennsylvania	PA	PA–23	1,381,890
North Penn Legal Services	PA	PA–24	2,062,365
MidPenn Legal Services	PA	PA–25	2,676,169
Northwestern Legal Services	PA	PA–26	755,956
Laurel Legal Services	PA	PA–5	692,809
Neighborhood Legal Services Association	PA	PA–8	1,450,732
Puerto Rico Legal Services	PR	MPR	65,462
Puerto Rico Legal Services	PR	PR–1	11,959,727
Community Law Office	PR	PR–2	218,518
Rhode Island Legal Services	RI	RI–1	979,068
South Carolina Legal Services	SC	MSC	157,389
South Carolina Legal Services	SC	SC–8	6,110,405
Dakota Plains Legal Services	SD	NSD–1	1,037,866
East River Legal Services	SD	SD–2	435,883
Dakota Plains Legal Services	SD	SD–4	473,562
Legal Aid Society of Middle TN and the Cumberlands	TN	TN–10	3,163,159
Memphis Area Legal Services	TN	TN–4	1,569,486
West Tennessee Legal Services	TN	TN–7	723,357
Legal Aid of East Tennessee	TN	TN–9	2,554,076
Texas RioGrande Legal Aid	TX	MSX–2	1,966,413
Texas RioGrande Legal Aid	TX	NTX–1	34,789
Lone Star Legal Aid	TX	TX–13	12,178,339
Legal Aid of NorthWest Texas	TX	TX–14	9,254,777

Name of applicant organization	State	Service area	Estimated annualized 2020 funding
Texas RioGrande Legal Aid	TX	TX–15	11,639,168
Utah Legal Services	UT	MUT	94,085
Utah Legal Services	UT	NUT–1	91,447
Utah Legal Services	UT	UT–1	2,377,963
Central Virginia Legal Aid Society	VA	MVA	189,860
Southwest Virginia Legal Aid Society	VA	VA–15	877,436
Legal Aid Society of Eastern Virginia	VA	VA–16	1,589,575
Virginia Legal Aid Society	VA	VA–17	817,682
Central Virginia Legal Aid Society	VA	VA–18	1,326,608
Blue Ridge Legal Services	VA	VA–19	871,591
Legal Services of Northern Virginia	VA	VA–20	1,616,813
Legal Services of the Virgin Islands	VI	VI–1	196,919
Legal Services Law Line of Vermont	VT	VT–1	527,603
Northwest Justice Project	WA	MWA	716,196
Northwest Justice Project	WA	NWA–1	316,647
Northwest Justice Project	WA	WA–1	5,970,518
Legal Action of Wisconsin	WI	MWI	405,064
Wisconsin Judicare	WI	NWI–1	172,427
Wisconsin Judicare	WI	WI–2	1,021,819
Legal Action of Wisconsin	WI	WI–5	3,904,457
Legal Aid of West Virginia	WV	WV–5	2,803,358
Legal Aid of Wyoming	WY	NWY–1	192,082
Legal Aid of Wyoming	WY	WY–4	533,955

These grants will be awarded under the authority conferred on LSC by section 1006(a)(1) of the Legal Services Corporation Act, 42 U.S.C. 2996e(a)(l). Grant awards are made to ensure civil legal services are provided in every service area, although no listed organization is guaranteed a grant award. Grants will become effective, and grant funds will be distributed, on or about January 1, 2020.

LSC issues this notice pursuant to 42 U.S.C. 2996f(f). Comments and recommendations concerning potential grantees are invited and should be delivered to LSC within 30 days from the date of publication of this notice.

Dated: October 30, 2019.

Stefanie Davis,

Assistant General Counsel.

[FR Doc. 2019–24039 Filed 11–1–19; 8:45 am]

BILLING CODE 7050–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2020–002]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: We are providing notice that we have requested Office of Management and Budget renewal of an information collection, Freedom of Information Act (FOIA) Request for Assistance and Consent. Our Office of Government Information Services collects this information and consent from people who request mediation services related to their FOIA requests or appeals. We need the information in order to meet Privacy Act requirements for agencies to release information to us as part of our mediation efforts. We invite comments on the proposed information collection.

DATES: Submit comments in writing to OMB at the address below on or before December 4, 2019 to be considered.

ADDRESSES: Send comments to Nicholas Fraser, NARA Desk Officer, by mail to Office of Management and Budget; New Executive Office Building; Washington, DC 20503, by fax to 202.395.5167, or by email to *Nicholas_A._Fraser@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information or copies of the proposed information collection and supporting statement to Tamee Fechhelm at phone number 301.837.1694 or fax number 301.837.7409.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), NARA invites the public and other Federal agencies to comment on proposed information collections. We published a notice of proposed collection for this information collection on August 26, 2019 (84 FR 44641). We received no comments. We have therefore submitted the described information collection to OMB for approval.

In response to this notice, comments and suggestions should address one or more of the following points: (a) Whether the proposed information collection is necessary for the our to properly perform our functions; (b) the accuracy of our estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information being collected; (d) ways to minimize the burden of the information collection on respondents, including the use of information technology; and (e) whether small businesses are affected by this collection. In this notice, we solicit comments on the following information collection:

Title: Freedom of Information Act (FOIA) Request for Assistance and Consent.

OMB number: 3095–0068.

Agency form number: NA Form 10003.

Type of review: Regular.

Affected public: Individuals or households, business or other for-profit, not-for-profit institutions, and Federal Government.

Estimated number of respondents: 3,646.

Estimated time per response: Ten minutes.

Frequency of response: On occasion.

Estimated total annual burden hours: 608 hours.

Abstract: In order to fulfill its Government-wide statutory mission to mediate FOIA disputes between requesters and agencies, OGIS must communicate with Government departments and agencies regarding the

customer's FOIA/Privacy Act of 1974 request or appeal. As a result, OGIS collects intake information from customers who request OGIS's mediation services. This information includes the customer's name, contact information, FOIA case number, information on the customer's concern areas/resolution goals, and documents relating to the underlying Freedom of Information Act/Privacy Act request or appeal. Customers provide this information by phone, fax, email, or mail.

OGIS and other agencies must handle FOIA and Privacy Act-protected case information in conformity with the requirements of the FOIA and Privacy Act, including 5 U.S.C. 552a(b), which prohibits agencies from releasing Privacy-Act protected information without an already-established routine use or consent of the person to whom the information pertains. In accord with this requirement, a subset of customers also must fill out a privacy consent form, NA Form 10003, if dealing with an agency that has not published a system of records notice with a routine use for release of information to OGIS.

OGIS uses the information customers provide in this information collection to contact customers, request information on the customer's case from other Federal agencies, and provide the requested assistance. Without the information submitted in the intake process and the consent form, OGIS would be unable to get the information from other agencies or fulfill its mediation mission.

Swarnali Haldar,

Executive for Information Services/CIO.

[FR Doc. 2019–23965 Filed 11–1–19; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL FOUNDATION FOR THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

Notice of Proposed Information Collection Request: Evaluation of the Boston Children's Museum's Building a National Network of Museums and Libraries for School Readiness (SRP) Project

AGENCY: Institute of Museum and Library Services, National Foundation for the Arts and the Humanities.

ACTION: Notice, request for comments on this collection of information.

SUMMARY: The Institute of Museum and Library Services (IMLS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act. This pre-clearance consultation 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. This action is to create the overall evaluation plan, survey, and data collection instruments and instructions for the various evaluation techniques to be used at different points in the development and implementation of the SRP project for the next three years.

A copy of the proposed information collection request can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before December 31, 2019.

IMLS is particularly interested in comments that help the agency to:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques, or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

ADDRESSES: Send comments to: Kim Miller, Director, Office of Grants Policy and Management, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW, Suite 4000, Washington, DC 20024–2135. Ms. Miller can be reached by Telephone: 202–653–4762, or by email at *kmiller@imls.gov,* or by teletype (TTY/TDD) for persons with hearing difficulty at 202–653–4614.

FOR FURTHER INFORMATION CONTACT: Reagan Moore, Museum Program Officer, Office of Museum Services, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW, Suite 4000, Washington, DC 20024–2135. She can be reached by Telephone: 202–653–4637; Fax: 202–653–4608; email at *rmoore@imls.gov;* or teletype (TTY/TDD) for persons with hearing difficulty at 202–653–4614.

SUPPLEMENTARY INFORMATION:

I. Background

The Institute of Museum and Library Services is the primary source of federal support for the nation's libraries and museums. We advance, support, and empower America's museums, libraries, and related organizations through grant making, research, and policy development. Our vision is a nation where museums and libraries work together to transform the lives of individuals and communities. To learn more, visit *www.imls.gov.*

II. Current Actions

The *Building a National Network of Museums and Libraries for School Readiness* (SRP) is a project funded by IMLS that seeks to undertake a multilevel approach to expanding nationwide the IMLS-funded School Readiness through Partnerships model that addresses persistent gaps in early childhood education and school readiness. The goal of the SRP is to amplify the strength of organizations serving children and families by forming coalitions that ensure all children in their regions, regardless of socio-economic or linguistic background, have the skills needed to enter school prepared for success. Strongly aligned with the IMLS's goal to build capacity for museum and library staff, the SRP will engage six states and institutions nationwide in harnessing the power of museums and libraries to support school readiness.

Over the three year project timeline, BCM will maintain and continuously improve existing networks in Massachusetts; scale existing efforts in South Carolina and Virginia; pilot grassroots museum and library networks in three additional states (TBD) in collaboration with the BUILD Initiative (''BUILD''); and develop sustainability mechanisms for the network within and among the states. By the end of three years, there will be six statewide networks in sustaining mode nationwide. All of this will be done in consultation with IMLS. The Education Development Center (EDC) will serve as the third-party evaluator for the project, documenting the progress and testing the effectiveness of the model in building institutional readiness to serve families in their regions. The evaluation

will accomplish three key goals: (1) Document project activities and implement the network model, (2) identify institutional capacities and cross-organizational relationships that support model outreach, implementation, and sustainability, and (3) assess the perceived impact of the model among hub leaders, key partners, collaborating organizations, and participating families. EDC will use a mixed-methods design, pairing quantitative survey data with qualitative interview data.

The current action is to create the overall evaluation plan, survey, and data collection instruments and instructions for the evaluation techniques to be used at different points in the development and implementation of the SRP project over the next three years.

Agency: Institute of Museum and Library Services.

Title: Building a National Network of Museums and Libraries for School Readiness Evaluation.

OMB Number: 3137–TBD.

Frequency: Once.

Affected Public: Museum staff, library staff, families.

Number of Respondents: TBD.

Estimated Average Burden per Response: TBD hours.

Estimated Total Annual Burden: TBD hours.

Total Annualized capital/startup costs: N/A.

Total Annual costs: TBD.

Public Comments Invited: Comments submitted in response to this notice will be summarized and/or included in the request for OMB's clearance of this information collection.

Dated: October 30, 2019.

Kim Miller,

Grants Management Specialist,Institute of Museum and Library Services.

[FR Doc. 2019–24010 Filed 11–1–19; 8:45 am]

BILLING CODE 7036–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meeting; National Science Board

The National Science Board's External Engagement Committee's Subcommittee on Honorary Awards, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business, as follows:

TIME & DATE: November 6, 2019, from 5:00–6:00 p.m. EST.

PLACE: This meeting will be held by teleconference at the National Science Foundation, 2415 Eisenhower Ave., Alexandria, VA 22314.

STATUS: Closed.

MATTERS TO BE CONSIDERED: (1) Subcommittee Chair's opening remarks; (2) Review and discuss candidates for the 2020 National Science Board Honorary Awards—the Vannevar Bush Award and the NSB Public Service Award; and subcommittee Chair's closing remarks.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Faith Hixson, 2415 Eisenhower Ave., Alexandria, VA 22314, *fhixson@nsf.gov,* (703) 292–7000. Meeting information and updates may be found at *http://www.nsf.gov/nsb/meetings/notices.jsp#sunshine.* Please refer to the National Science Board website *www.nsf.gov/nsb* for general information.

Chris Blair,

Executive Assistant to the NSB Office.

[FR Doc. 2019–24092 Filed 10–31–19; 11:15 am]

BILLING CODE 7555–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87412; File No. SR–ISE–2019–29]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Options 3, Section 17, the Exchange's Kill Switch Risk Protection

October 29, 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 October 15, 2019, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Options 3, Section 17, which sets forth the Exchange's optional Kill Switch risk protection.

The text of the proposed rule change is available on the Exchange's website at *http://ise.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 expand the optional Kill Switch risk protection the Exchange offers to Members today to allow cancellation and restriction of quotes, orders, or both. This new functionality will be offered alongside the existing port Kill Switch (as defined below), which currently allows Members to cancel and restrict only their orders. The Exchange also proposes to amend its rules to add more detail on how the port Kill Switch operates today. As discussed further below, no functional changes to the existing port Kill Switch functionality are being contemplated by this rule change; rather, the Exchange is providing more detailed information on the port Kill Switch so that the rule is more aligned with the current operation of existing functionality.

Port Kill Switch

Today, Kill Switch provides Members with a risk management tool for immediate control of their order activity. Specifically as set forth in Options 3, Section 17(a), Kill Switch enables Members to initiate a message [3] to the System [4] to promptly cancel

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Today, Members are able to send a message to the Exchange to initiate the Kill Switch. A Kill Switch message may be sent through the Exchange order entry ports FIX, OTTO, or Precise (hereinafter, referred to as ''port Kill Switch'').

[4] The term ''System'' means the electronic system operated by the Exchange that receives and

Continued

orders and restrict entry of new orders until re-entry has been enabled. Members may submit a request to the System to cancel orders for that Member. The System will send an automated message to the Member when a Kill Switch request has been processed by the Exchange's System.

If orders are cancelled by the Member utilizing the Kill Switch, it will result in the removal of all orders for the Member.[5] The Member is unable to enter additional orders until the Member has made a verbal request to the Exchange and Exchange staff has set a re-entry indicator to enable re-entry.[6] Once enabled for re-entry, the System will send a Re-entry Notification Message to the Member. The applicable Clearing Member for that Member will also be notified of the re-entry into the System after orders are cancelled as a result of the Kill Switch, provided the Clearing Member has requested to receive such notification.

The Exchange now proposes to provide additional detail regarding the port Kill Switch described above to better align the Rule with existing system functionality. The Exchange proposes to clarify that Members may submit a Kill Switch request to the System through FIX, OTTO, or Precise for the Member's requested identifier (*i.e.,* badge[7] or mnemonic[8]) (''Identifier'') on a user level (*i.e.,* by individual badge or mnemonic).[9] As such, Members using the port Kill Switch today may elect to cancel all existing orders and restrict entry of additional orders by individual badge/mnemonic (*i.e.,* Identifier). Furthermore, if the Member's requested Identifier(s) is enabled to trade on both the Exchange and the Exchange's affiliate, Nasdaq GEMX (''GEMX''), the port Kill Switch applies across both ISE and GEMX.[10] If a Member chooses to configure its Identifier on ISE but not GEMX, the port Kill Switch activated on ISE will only apply to that Identifier on ISE.

While the current rule text does not specifically provide for these two features (*i.e.,* the ability to cancel and restrict orders by individual Identifier(s) and, if set by the Member, across both ISE and GEMX), the existing port Kill Switch functionality operates in this manner today. Accordingly, the Exchange proposes to replace the existing language in section (a)(1) with the following to make clear how the System operates today: ''A Member may submit a request to the System through FIX, OTTO, or Precise to cancel all existing orders and restrict entry of additional orders for the requested Identifier(s) on a user level on Nasdaq ISE, or across both Nasdaq ISE and Nasdaq GEMX, in either case as set by the Member.''

As noted above, the Exchange is not proposing any functional modifications to the existing port Kill Switch; rather, all of the changes proposed above are to provide additional specificity as to how the port Kill Switch operates today for greater consistency between the rule text and the operation of the System. Lastly, the Exchange proposes to delete the last sentence of (a)(1), which is redundant with the re-entry provisions already set forth in the Rule.[11]

GUI Kill Switch

The Exchange also proposes to add new functionality that would enhance the current Kill Switch risk protection for orders to apply to both orders and quotes.[12] The Exchange will provide this enhancement through a separate graphical user interface (hereinafter, ''GUI Kill Switch'') as an alternative way for Members to manage their trading activity.[13] As discussed below, the new GUI Kill Switch will be functionally similar to the existing port Kill Switch, with the most notable difference being the added ability to cancel all existing quotes and block the entry of additional quotes. For instance, similar to the port Kill Switch today, Members will be able to use the GUI Kill Switch for requested Identifier(s) to apply either on ISE only or across both ISE and GEMX, depending on how the Identifier(s) was set up by the Member. Accordingly, Options 3, Section 17 will be amended to reflect that the Exchange will offer the proposed GUI Kill Switch alongside the existing port Kill Switch. In particular, paragraph (a) will provide that Kill Switch would enable Members to initiate a message to the System to promptly cancel and restrict their quote and order activity on Nasdaq ISE, or across both ISE and GEMX, as further described in the Rule. The Exchange also proposes to specify that Members may submit a Kill Switch request to the System for certain Identifier(s) on either a user or group level. Permissible groups must reside within a single Member firm.[14]

As discussed above, while the proposed language in section (a) on applying Kill Switch for requested Identifier(s) across both ISE and GEMX is new, these features exist today with respect to the port Kill Switch. Accordingly, the proposed changes in (a) with respect to order cancellation and restriction clarify the current manner in which the port Kill Switch operates today, and also extends the rule to encompass the proposed GUI Kill Switch.

The Exchange further proposes to describe the new GUI Kill Switch functionality in new section (a)(2).[15] Specifically, the Exchange proposes to add the following: ''Alternatively, a Member may submit a request to the System through a graphical user interface to cancel all existing, and restrict entry of additional, quotes and/or orders for the requested Identifier(s) on either a user or group level on Nasdaq ISE, or across both Nasdaq ISE

disseminates quotes, executes orders and reports transactions. *See* Options 1, Section 1(a)(48).

[5] Members may not cancel orders by symbol. Of note, Opening Sweeps are also cancelled. An Opening Sweep is a Market Maker order submitted for execution against eligible interest in the system during the Opening Process pursuant to Options 3, Section 8(b)(1). *See* Options 3, Section 7(u). Consistent with current auction functionality, PIM auction orders and responses are not cancelled. PIM is the Exchange's price improvement mechanism. *See* Options 3, Section 13. Other auctions orders and responses are cancelled.

[6] The Member must directly and verbally contact the Exchange to request the re-set.

[7] A ''badge'' shall mean an account number, which may contain letters and/or numbers, assigned to Market Makers. A Market Maker account may be associated with multiple badges. *See* Options 1, Section 1(a)(4).

[8] A ''mnemonic'' shall mean an acronym comprised of letters and/or numbers assigned to Electronic Access Members. An Electronic Access Member account may be associated with multiple mnemonics. *See* Options 1, Section 1(a)(22).

[9] Using the port Kill Switch, Members are only able to cancel and restrict their order activity at the user level (*i.e.,* by individual Identifier). As discussed below, the new Kill Switch enhancement will offer Members the additional option of submitting requests at the user level or group level—in other words, by individual Identifier or for a group of Identifiers. *See, e.g.,* Nasdaq Options Market (''NOM'') Chapter VI, Sec. 6(d), which sets forth NOM's Kill Switch rule, for similar terminology related to Identifier.

[10] Thus, for example, an Electronic Access Member that is configured to trade on ISE and GEMX in mnemonics ABCD1, ABCD2, and ABCD3 would submit a separate request for each mnemonic using the port Kill Switch, which would result in the cancellation of all existing orders and the restriction of additional orders associated with mnemonics ABCD1, ABCD2, and ABCD3 across both ISE and GEMX. The ability to kill interest across both ISE and GEMX is a feature that was carried over from the Exchange's previous T7 trading system.

[11] *See* Options 3, Section 17(a)(2). As discussed below, this section will be renumbered as section (a)(3) under this proposal.

[12] As discussed more fully later in the filing, the proposed Kill Switch enhancement will also have additional features to allow Members to kill quotes and/or orders for requested Identifier(s) on either a user or group level.

[13] The GUI Kill Switch will be available to all Members through a web-based interface.

[14] For example, a permissible group could include all badges associated with a Market Maker. Member would be able to set up these groups beforehand to include all or some of the Identifiers associated with the Member firm so that a GUI Kill Switch request could apply to this pre-defined group.

[15] In light of adopting this new section, current (a)(2) will be renumbered as (a)(3).

and Nasdaq GEMX, in either case as set by the Member.'' [16]

The Exchange believes that the proposed enhancement to the Kill Switch will offer Members an alternative means to control their exposure, through a separate interface which is not dependent on the integrity of the member's own systems, should the member experience a failure. Because the proposed enhancement will be provided through a separate user interface instead of one of the Exchange's order entry ports, the Exchange believes it would promote transparency in its Rules to separately define these alternative methods in (a)(1) and (a)(2). As noted above, the proposed enhancement is similar to the existing port Kill Switch that allows Members to control their order activity but has additional optionality, most significantly the ability to cancel and restrict quotes, orders, or both. Furthermore, Members can set up the GUI Kill Switch so they are able to control their quote and/or order activity for an individual Identifier or a group of Identifiers,[17] as compared to the port Kill Switch which is limited to individual Identifiers only.[18]

The re-entry provisions in section (a)(3) will also be amended throughout to reflect that the re-entry process after initiating the GUI Kill Switch will be identical to the current process for the port Kill Switch. Specifically, once a Member initiates either the port or GUI Kill Switch, the Member will be unable to enter additional orders, and/or quotes if pursuant to the GUI Kill Switch, for the affected Identifier(s) until the Member has made a verbal request to the Exchange and Exchange staff has set a re-entry indicator to enable re-entry.[19] Lastly, the Exchange proposes to make a related change in the last sentence of section (a)(3) to delete the reference to order cancellation, and also provide that the ''applicable Clearing Member will be notified of *such* re-entry. . .'' for better readability.

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, by enhancing the risk protections available to Members. The proposal promotes policy goals of the Commission which has highlighted the need for execution venues, exchange and non-exchange alike, to enhance risk protection tools and other mechanisms to decrease risk and increase stability.[22]

The proposed GUI Kill Switch, similar to the existing port Kill Switch, is designed to protect Members in the event the Member encounters a situation, like a systems issue, for which they would need to withdraw temporarily from the market. The individual Member firm benefits of enhanced risk protections, including Kill Switch mechanisms, flow downstream to counter-parties both at the Exchange and at other options exchanges, thereby increasing systemic protections as well. Additionally, because the Exchange will continue offer this optional risk tool to all Members, the Exchange believes that it will encourage liquidity generally and remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest. To the extent the Exchange's proposal provides Members with greater control over their quotes and orders, and allows them to remove quotes and cancel orders in an appropriate manner, then the proposal may encourage Members to provide liquidity on ISE and thus contribute to fair and orderly markets in a manner that protects the public interest and protects investors.

As noted above, this optional risk tool will continue to be offered to all Members. The Exchange further represents that its proposal will continue to operate consistently with the firm quote obligations of a broker-dealer pursuant to Rule 602 of Regulation NMS and that the functionality is not mandatory. Specifically, any interest that is executable against a Member's orders or quotes that are received [23] by the Exchange, prior to the time the Kill Switch is processed by the System, will automatically execute at the price up to the Member's size. The Kill Switch message will be accepted by the System in the order of receipt in the queue and will be processed in that order so that interest that is already accepted into the System will be processed prior to the Kill Switch message. Messages sent to the System by the Kill Switch are processed in the order they are received by the matching engine, through the same queuing mechanism that a quote or order message is processed. The Exchange also notes that the latency profile of the GUI Kill Switch is comparable to the latency profile of killing interest through a message based Kill Switch from a Member's order entry port.

A Market Maker's obligation to provide two-sided quotes on a daily basis is not diminished by the removal of such quotes and/or orders by utilizing the Kill Switch. Market Makers that utilize Kill Switch will not be relieved of the obligation to provide intra-day quotes pursuant to Options 2, Section 5(e), nor will it prohibit the Exchange from taking disciplinary action against a Market Maker for failing to meet its quoting obligations each trading day.

The proposed changes will also permit Clearing Members that clear transactions on a Member's behalf pursuant to a Letter of Guarantee [24] to receive information regarding the Member's re-entry into the System after

[16] Members may not cancel orders and quotes by symbol using the GUI Kill Switch, similar to how orders may not be cancelled by symbol through the port Kill Switch today. Also similar to the port Kill Switch, Opening Sweeps will be cancelled upon initiating the GUI Kill Switch. Lastly, all auction orders and responses other than PIM orders/responses will similarly be cancelled. *See supra* note 5.

[17] As noted above, NOM Chapter VI, Sec. 6(d) has similar terminology in its Kill Switch rule. *See supra* note 9. Furthermore, the proposed GUI Kill Switch is functionally similar to NOM's Kill Switch in that both are offered through a separate graphical user interface and have similar features, including the ability for members to apply Kill Switch for certain identifiers on a user or group level.

[18] As an example of the GUI Kill Switch, assume a Market Maker is configured to trade on ISE and GEMX in badges 123A, 123B, and 123C, with pre-defined settings that include all three badges as one group to which the GUI Kill Switch will apply. The Market Maker could then submit a GUI Kill Switch request to restrict their quote activity for the pre-defined group, resulting in the cancellation of all existing quotes and restriction of additional quotes associated with badges 123A, 123B, and 123C across both ISE and GEMX. The same Market Maker could instead opt to submit a GUI Kill Switch request for only badge 123A to cancel all existing quotes and restrict entry of additional quotes for that individual badge. The proposed functionality therefore allows the Member to have more optionality as compared to the existing mechanism.

[19] Identical to re-entry for the port Kill Switch, Members must directly and verbally contact the Exchange to request the re-set if they initiate the GUI Kill Switch. *See supra* note 6 with accompanying text.

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(5).

[22] *See, e.g.,* Securities Exchange Act Release Nos. 69077 (March 8, 2013), 78 FR 18083 (March 25, 2013) (Proposing Release) at 18090–91; and 73639 (November 19, 2014), 79 FR 72251 (December 5, 2014) (Adopting Release) at 72253 (highlighting that quality standards, testing and improved error response mechanisms are among the issues needing very thoughtful and focused attention in today's securities markets).

[23] The time of receipt for an order or quote is the time such message is processed by the Exchange's order book.

[24] A Letter of Guarantee obligates the issuing Clearing Member to accept financial responsibilities for all Exchange transactions made by the guaranteed Member. *See* Options 6, Section 4(a) and (b).

the Member initiates the GUI Kill Switch, and makes the verbal request to the Exchange for re-entry pursuant to Options 3, Section 17(a). As is the case today with the port Kill Switch, because such Clearing Members guarantee all transactions on behalf of that Member and therefore bear the risk associated with those transactions, the Exchange believes that it is appropriate for the Clearing Member to receive information regarding re-entry into the System after quotes and/or orders are cancelled as a result of the GUI Kill Switch, should the Clearing Member request such notification. This information may help provide Clearing Members with greater control and flexibility in managing the risk associated with the Member's activity.

The Exchange's proposal also extends the cross-market feature available today through the port Kill Switch to the proposed GUI Kill Switch. The Exchange notes that issues that would prompt a Member to submit a Kill Switch request are normally not confined to a member's activity on a single exchange. Accordingly, the Exchange believes that offering both the port and GUI Kill Switch protections on a cross-market basis would help Members to more effectively manage their risk when trading on multiple markets, and reduce disruptive trading events to the benefit of all members and investors. For the same reasons, the Exchange already offers other cross market risk protections pursuant to the Market Wide Risk Protection (''MWRP'') [25] as well as for market maker quotes, both of which can be applied across ISE and GEMX similar to the port and GUI Kill Switch.[26] Like MWRP and the cross-market protections for market maker quotes, the Exchange ported over the Kill Switch's cross-market feature from the Exchange's previous trading system with minimal modifications to minimize the impact to Members that were already familiar with the existing risk management tools.

Lastly, the Exchange believes that the proposed changes to add greater specificity with respect to how the port Kill Switch currently operates (*i.e.,* that a Kill Switch request sent through FIX, OTTO, or Precise will result in the cancellation of all existing orders, and restrict entry of additional orders for the requested Identifier(s) on a user level on ISE, or across both ISE and GEMX, in either case as set by the Member) will promote greater transparency around the existing Kill Switch, and will serve to better align the Exchange's rules with current System functionality, to the benefit of investors and the public interest.

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 proposal does not impose an undue burden on intramarket competition because all Members may avail themselves of the Kill Switch. The Kill Switch risk protection is optional. The proposed rule change to expand this risk protection to encompass quote cancellation and restriction will further protect Members in the event the Member is suffering from a systems issue or from the occurrence of unusual or unexpected market activity that would require them to withdraw from the market in order to protect investors. As discussed above, the proposed GUI Kill Switch, like the existing port Kill Switch, would be offered cross-market to Members that want to be protected from inadvertent exposure to excessive risk when trading on both ISE and GEMX. The Exchange does not believe that permitting this functionality to be cross-market will impose any undue burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the target of the cross-market feature is to reduce risk for Members that trade on ISE and GEMX. As noted above, issues that would prompt a Member to submit a Kill Switch request are normally not confined to a Member's activity on a single exchange, so the Exchange believes that having the ability to manage risk across more than one market will ultimately be beneficial by providing Members with greater control over their quotes and orders, which may reduce disruptive trading events to the benefit of all investors and the public interest. Finally, the Exchange notes other exchanges, including the Exchange's affiliated options markets, similarly offer Kill Switch protections for both quotes and orders.[27]

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 [28] and subparagraph (f)(6) of Rule 19b–4 thereunder.[29]

A proposed rule change filed under Rule 19b–4(f)(6) [30] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[31] the Commission may 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. According to the Exchange, waiver of the operative delay is consistent with the protection of investors and the public interest because it would provide Members with greater control over their quotes and orders, which may reduce disruptive trading events to the benefit of all investors and the public interest. The Exchange notes that similar kill switch protections are available on other options exchanges and that the Commission has previously approved similar cross market risk protections,[32] and that as such, the proposed rule change does not raise any new, unique or substantive issues. 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

[25] *See* Options 3, Section 15(b)(1)(D).

[26] *See* Options 3, Section 15(b)(3)(B)(vi).

[27] The proposed GUI Kill Switch protections are similar to those available on its affiliated options markets Nasdaq BX (''BX''), NOM, and Nasdaq Phlx (''Phlx''), except BX, NOM, and Phlx Kill Switches do not apply cross-market to other affiliated exchanges. As discussed above, the proposed GUI Kill Switch may apply across ISE and GEMX, if set by the Exchange member. *See* BX Chapter VI, Section 6(d); NOM Chapter VI, Section 6(d); and Phlx Rule 1019(b). *See also* CBOE Exchange Rule 5.34(c)(7) and BOX Options Exchange Rule 7280(b) for other options exchanges that offer Kill Switch protections for quotes and orders.

[28] 15 U.S.C. 78s(b)(3)(A)(iii).

[29] 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.

[30] 17 CFR 240.19b–4(f)(6).

[31] 17 CFR 240.19b–4(f)(6)(iii).

[32] *See supra* notes 25–27 and accompanying text.

designates the proposed rule change operative upon filing.[33]

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–ISE–2019–29 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–ISE–2019–29. 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–ISE–2019–29 and should be submitted on or before November 25, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–23974 Filed 11–1–19; 8:45 am]

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[33] 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).

[34] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87415; File No. 4–753]

Self-Regulatory Organizations; Long-Term Stock Exchange, Inc.; Order Declaring Effective a Minor Rule Violation Plan

October 29, 2019.

On August 23, 2019, Long-Term Stock Exchange, Inc. (''LTSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed minor rule violation plan (''MRVP'') pursuant to Section 19(d)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19d–1(c)(2) thereunder.[2] The proposed MRVP was published for comment on September 25, 2019.[3] The Commission received no comments on the proposal. This order declares the Exchange's proposed MRVP effective.

In accordance with Rule 19d–1(c)(2) under the Act,[4] the Exchange proposed to designate certain specified rule violations as minor rule violations, with sanctions not exceeding $2,500. Violations resolved under the MRVP would not be subject to the provisions of Rule 19d–1(c)(1) of the Act,[5] which requires that a self-regulatory organization (''SRO'') promptly file notice with the Commission of any final disciplinary action taken with respect to any person or organization.[6] In accordance with Rule 19d–1(c)(2) under the Act,[7] the Exchange proposed to designate certain specified rule violations as minor rule violations, and requested that it be relieved of the prompt reporting requirements regarding such violations, provided it gives notice of such violations to the Commission on a quarterly basis.

The Exchange proposed to include in its MRVP the procedures included in LTSE Rule 9.216(b) (''Procedure for Violation Under Plan Pursuant to Exchange Act Rule 19d–1(c)(2)'') and violations included in Rule 9.218 (''Violations Appropriate for Disposition Under Plan Pursuant to Exchange Act Rule 19d–1(c)(2)'').[8] According to the Exchange's proposed MRVP, the Exchange may impose a fine (not to exceed $2,500) and/or a censure on any Member or its associated person with respect to any rule listed in LTSE Rule 9.218. If the Financial Industry Regulatory Authority's (''FINRA'') Department of Enforcement or Department of Market Regulation, on behalf of the Exchange, has reason to believe a violation has occurred, and if the Member or its associated person does not dispute the violation, either Department may prepare and request that the Member or associated person execute a minor rule violation plan letter. The letter would describe the act or practice engaged in or omitted, the rule, regulation, or statutory provision

[1] 15 U.S.C. 78s(d)(1).

[2] 17 CFR 240.19d–1(c)(2).

[3] *See* Securities Exchange Act Release No. 87021 (September 19, 2019), 84 FR 50525 (''Notice'').

[4] 17 CFR 240.19d–1(c)(2).

[5] 17 CFR 240.19d–1(c)(1).

[6] The Commission adopted amendments to paragraph (c) of Rule 19d–1 to allow SROs to submit for Commission approval plans for the abbreviated reporting of minor disciplinary infractions. *See* Securities Exchange Act Release No. 21013 (June 1, 1984), 49 FR 23828 (June 8, 1984). Any disciplinary action taken by an SRO against any person for violation of a rule of the SRO which has been designated as a minor rule violation pursuant to a plan filed with and declared effective by the Commission is not considered ''final'' for purposes of Section 19(d)(1) of the Act if the sanction imposed consists of a fine not exceeding $2,500 and the sanctioned person has not sought an adjudication, including a hearing, or otherwise exhausted his administrative remedies.

[7] 17 CFR 240.19d–1(c)(2).

[8] The Commission granted the Exchange's application for registration as a national securities exchange on May 10, 2019, which included the rules that govern the Exchange. *See* Securities Exchange Act Release No. 85828 (May 10, 2019), 84 FR 21841 (May 15, 2019). Terms not otherwise defined in this Order are defined in the LTSE rules.

Under the proposed MRVP, violations of the following rules would be appropriate for disposition under the MRVP: Rule 2.160(p) (Continuing Education Requirements); Rule 4.511 (General Requirements related to books and records requirements); Rule 4.540 (Furnishing of Records); Rule 5.110 (Supervision); Rule 8.220 (Automated Submission of Trading Data Requested); Rule 11.151(a)(1) (Market Maker Two-sided Quote Obligation); Rule 11.290 (Short Sales); Rule 11.310 (Locking or Crossing Quotations in NMS Stocks); and Rule 11.420 (Order Audit Trail System Requirements). *See* Notice, *supra* note 3, at 50526.

violated, and the sanction or sanctions to be imposed. The letter, if accepted, would stipulate that the Member or associated person accepts the finding of violation, consents to the imposition of sanctions, and agrees to waive such Member's or associated person's right to a hearing before a Hearing Panel or, if applicable, an Extended Hearing Panel, and any right of appeal to the LTSE Appeals Committee, the Board, the Commission, and the courts, or to otherwise challenge the validity of the letter. Unless the letter states otherwise, the effective date of any sanction(s) imposed would be a date to be determined by LTSE Regulation staff. In the event the letter is not accepted by the Member or associated person, or is rejected by FINRA's Office of Disciplinary Affairs, the matter can proceed in accordance with the Exchange's disciplinary rules, which include hearing rights for formal disciplinary proceedings.[9]

According to the Exchange, upon the Commission's declaration of effectiveness of the MRVP, the Exchange will provide to the Commission a quarterly report for any actions taken on minor rule violations under the MRVP.[10] The quarterly report will include: The Exchange's internal file number for the case, the name of the individual and/or organization, the nature of the violation, the specific rule provision violated, the sanction imposed, the number of times the rule violation occurred, and the date of the disposition.[11]

The Exchange requested that the Commission deem any changes to the rules applicable to the Exchange's MRVP to be deemed modifications to the Exchange's MRVP.[12]

The Commission finds that the proposal is consistent with the public interest, the protection of investors, or otherwise in furtherance of the purposes of the Act, as required by Rule 19d–1(c)(2) under the Act,[13] because the MRVP will permit the Exchange to carry out its oversight and enforcement responsibilities as an SRO more efficiently in cases where formal disciplinary proceedings are not necessary due to the minor nature of the particular violation.

In declaring the Exchange's MRVP effective, the Commission does not minimize the importance of compliance with Exchange rules and all other rules subject to the imposition of sanctions under LTSE Rule 9.216(b). Violation of an SRO's rules, as well as Commission rules, is a serious matter. However, LTSE Rule 9.216(b) provides a reasonable means of addressing violations that do not rise to the level of requiring formal disciplinary proceedings, while providing greater flexibility in handling certain violations. Regarding whether a violation requires formal disciplinary action or whether a sanction under the MRVP is appropriate, the Commission expects the Exchange to continue to conduct surveillance and make determinations based on its findings on a case-by-case basis.

It is therefore ordered, pursuant to Rule 19d–1(c)(2) under the Act,[14] that the proposed MRVP for Long-Term Stock Exchange, Inc, File No. 4–753 be, and hereby is, declared effective.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Jill M. Peterson,

Assistant Secretary.

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[9] *See* Notice, *supra* note 3, at 50526.

[10] *See Id.*

[11] The Exchange attached a sample form of the quarterly report with its submission to the Commission.

[12] *See* Notice, *supra* note 3, at 50526.

[13] 17 CFR 240.19d–1(c)(2).

[14] *Id.*

[15] 17 CFR 200.30–3(a)(44).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87413; File No. SR–GEMX–2019–15]

Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Options 3, Section 17, the Exchange's Kill Switch Risk Protection

October 29, 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 October 15, 2019, Nasdaq GEMX, LLC (''GEMX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[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 amend Options 3, Section 17, which sets forth the Exchange's optional Kill Switch risk protection.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqgemx.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 expand the optional Kill Switch risk protection the Exchange offers to Members today to allow cancellation and restriction of quotes, orders, or both. This new functionality will be offered alongside the existing port Kill Switch (as defined below), which currently allows Members to cancel and restrict only their orders. The Exchange also proposes to amend its rules to add more detail on how the port Kill Switch operates today. As discussed further below, no functional changes to the existing port Kill Switch functionality are being contemplated by this rule change; rather, the Exchange is providing more detailed information on the port Kill Switch so that the rule is more aligned with the current operation of existing functionality.

Port Kill Switch

Today, Kill Switch provides Members with a risk management tool for immediate control of their order activity. Specifically as set forth in Options 3, Section 17(a), Kill Switch enables Members to initiate a message [3]

[3] Today, Members are able to send a message to the Exchange to initiate the Kill Switch. A Kill

to the System [4] to promptly cancel orders and restrict entry of new orders until re-entry has been enabled. Members may submit a request to the System to cancel orders for that Member. The System will send an automated message to the Member when a Kill Switch request has been processed by the Exchange's System.

If orders are cancelled by the Member utilizing the Kill Switch, it will result in the removal of all orders for the Member.[5] The Member is unable to enter additional orders until the Member has made a verbal request to the Exchange and Exchange staff has set a re-entry indicator to enable re-entry.[6] Once enabled for re-entry, the System will send a Re-entry Notification Message to the Member. The applicable Clearing Member for that Member will also be notified of the re-entry into the System after orders are cancelled as a result of the Kill Switch, provided the Clearing Member has requested to receive such notification.

The Exchange now proposes to provide additional detail regarding the port Kill Switch described above to better align the Rule with existing system functionality. The Exchange proposes to clarify that Members may submit a Kill Switch request to the System through FIX, OTTO, or Precise for the Member's requested identifier (*i.e.,* badge [7] or mnemonic [8]) (''Identifier'') on a user level (*i.e.,* by individual badge or mnemonic).[9] As such, Members using the port Kill Switch today may elect to cancel all existing orders and restrict entry of additional orders by individual badge/mnemonic (*i.e.,* Identifier). Furthermore, if the Member's requested Identifier(s) is enabled to trade on both the Exchange and the Exchange's affiliate, Nasdaq ISE (''ISE''), the port Kill Switch applies across both GEMX and ISE.[10] If a Member chooses to configure its Identifier on GEMX but not ISE, the port Kill Switch activated on GEMX will only apply to that Identifier on GEMX.

While the current rule text does not specifically provide for these two features (*i.e.,* the ability to cancel and restrict orders by individual Identifier(s) and, if set by the Member, across both GEMX and ISE), the existing port Kill Switch functionality operates in this manner today. Accordingly, the Exchange proposes to replace the existing language in section (a)(1) with the following to make clear how the System operates today: ''A Member may submit a request to the System through FIX, OTTO, or Precise to cancel all existing orders and restrict entry of additional orders for the requested Identifier(s) on a user level on Nasdaq GEMX, or across both Nasdaq GEMX and Nasdaq ISE, in either case as set by the Member.''

As noted above, the Exchange is not proposing any functional modifications to the existing port Kill Switch; rather, all of the changes proposed above are to provide additional specificity as to how the port Kill Switch operates today for greater consistency between the rule text and the operation of the System. Lastly, the Exchange proposes to delete the last sentence of (a)(1), which is redundant with the re-entry provisions already set forth in the Rule.[11]

GUI Kill Switch

The Exchange also proposes to add new functionality that would enhance the current Kill Switch risk protection for orders to apply to both orders and quotes.[12] The Exchange will provide this enhancement through a separate graphical user interface (hereinafter, ''GUI Kill Switch'') as an alternative way for Members to manage their trading activity.[13] As discussed below, the new GUI Kill Switch will be functionally similar to the existing port Kill Switch, with the most notable difference being the added ability to cancel all existing quotes and block the entry of additional quotes. For instance, similar to the port Kill Switch today, Members will be able to use the GUI Kill Switch for requested Identifier(s) to apply either on GEMX only or across both GEMX and ISE, depending on how the Identifier(s) was set up by the Member. Accordingly, Options 3, Section 17 will be amended to reflect that the Exchange will offer the proposed GUI Kill Switch alongside the existing port Kill Switch. In particular, paragraph (a) will provide that Kill Switch would enable Members to initiate a message to the System to promptly cancel and restrict their quote and order activity on GEMX, or across both GEMX and ISE, as further described in the Rule. The Exchange also proposes to specify that Members may submit a Kill Switch request to the System for certain Identifier(s) on either a user or group level. Permissible groups must reside within a single Member firm.[14]

As discussed above, while the proposed language in section (a) on applying Kill Switch for requested Identifier(s) across both GEMX and ISE is new, these features exist today with respect to the port Kill Switch. Accordingly, the proposed changes in (a) with respect to order cancellation and restriction clarify the current manner in which the port Kill Switch operates today, and also extends the rule to encompass the proposed GUI Kill Switch.

The Exchange further proposes to describe the new GUI Kill Switch functionality in new section (a)(2).[15] Specifically, the Exchange proposes to add the following: ''Alternatively, a

Switch message may be sent through the Exchange order entry ports FIX, OTTO, or Precise (hereinafter, referred to as ''port Kill Switch'').

[4] The term ''System'' means the electronic system operated by the Exchange that receives and disseminates quotes, executes orders and reports transactions. *See* Options 1, Section 1(a)(48).

[5] Members may not cancel orders by symbol. Of note, Opening Sweeps are also cancelled. An Opening Sweep is a Market Maker order submitted for execution against eligible interest in the system during the Opening Process pursuant to Options 3, Section 8(b)(1). *See* Options 3, Section 7(t). Consistent with current auction functionality, PIM auction orders and responses are not cancelled. PIM is the Exchange's price improvement mechanism. *See* Options 3, Section 13. Other auctions orders and responses are cancelled.

[6] The Member must directly and verbally contact the Exchange to request the re-set.

[7] A ''badge'' shall mean an account number, which may contain letters and/or numbers, assigned to Market Makers. A Market Maker account may be associated with multiple badges. *See* Options 1, Section 1(a)(4).

[8] A ''mnemonic'' shall mean an acronym comprised of letters and/or numbers assigned to Electronic Access Members. An Electronic Access Member account may be associated with multiple mnemonics. *See* Options 1, Section 1(a)(22).

[9] Using the port Kill Switch, Members are only able to cancel and restrict their order activity at the user level (*i.e.,* by individual Identifier). As discussed below, the new Kill Switch enhancement will offer Members the additional option of submitting requests at the user level or group level—in other words, by individual Identifier or for a group of Identifiers. *See, e.g.,* Nasdaq Options Market (''NOM'') Chapter VI, Sec. 6(d), which sets forth NOM's Kill Switch rule, for similar terminology related to Identifier.

[10] Thus, for example, an Electronic Access Member that is configured to trade on ISE and GEMX in mnemonics ABCD1, ABCD2, and ABCD3 would submit a separate request for each mnemonic using the port Kill Switch, which would result in the cancellation of all existing orders and the restriction of additional orders associated with mnemonics ABCD1, ABCD2, and ABCD3 across both ISE and GEMX. The ability to kill interest across both ISE and GEMX is a feature that was carried over from the Exchange's previous T7 trading system.

[11] *See* Options 3, Section 17(a)(2). As discussed below, this section will be renumbered as section (a)(3) under this proposal.

[12] As discussed more fully later in the filing, the proposed Kill Switch enhancement will also have additional features to allow Members to kill quotes and/or orders for requested Identifier(s) on either a user or group level.

[13] The GUI Kill Switch will be available to all Members through a web-based interface.

[14] For example, a permissible group could include all badges associated with a Market Maker. Member would be able to set up these groups beforehand to include all or some of the Identifiers associated with the Member firm so that a GUI Kill Switch request could apply to this pre-defined group.

[15] In light of adopting this new section, current (a)(2) will be renumbered as (a)(3).

Member may submit a request to the System through a graphical user interface to cancel all existing, and restrict entry of additional, quotes and/or orders for the requested Identifier(s) on either a user or group level on Nasdaq GEMX, or across both Nasdaq GEMX and Nasdaq ISE, in either case as set by the Member.'' [16]

The Exchange believes that the proposed enhancement to the Kill Switch will offer Members an alternative means to control their exposure, through a separate interface which is not dependent on the integrity of the member's own systems, should the member experience a failure. Because the proposed enhancement will be provided through a separate user interface instead of one of the Exchange's order entry ports, the Exchange believes it would promote transparency in its Rules to separately define these alternative methods in (a)(1) and (a)(2). As noted above, the proposed enhancement is similar to the existing port Kill Switch that allows Members to control their order activity but has additional optionality, most significantly the ability to cancel and restrict quotes, orders, or both. Furthermore, Members can set up the GUI Kill Switch so they are able to control their quote and/or order activity for an individual Identifier or a group of Identifiers,[17] as compared to the port Kill Switch which is limited to individual Identifiers only.[18]

The re-entry provisions in section (a)(3) will also be amended throughout to reflect that the re-entry process after initiating the GUI Kill Switch will be identical to the current process for the port Kill Switch. Specifically, once a Member initiates either the port or GUI Kill Switch, the Member will be unable to enter additional orders, and/or quotes if pursuant to the GUI Kill Switch, for the affected Identifier(s) until the Member has made a verbal request to the Exchange and Exchange staff has set a re-entry indicator to enable re-entry.[19] Lastly, the Exchange proposes to make a related change in the last sentence of section (a)(3) to delete the reference to order cancellation, and also provide that the ''applicable Clearing Member will be notified of *such* re-entry . . .'' for better readability.

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, by enhancing the risk protections available to Members. The proposal promotes policy goals of the Commission which has highlighted the need for execution venues, exchange and non-exchange alike, to enhance risk protection tools and other mechanisms to decrease risk and increase stability.[22]

The proposed GUI Kill Switch, similar to the existing port Kill Switch, is designed to protect Members in the event the Member encounters a situation, like a systems issue, for which they would need to withdraw temporarily from the market. The individual Member firm benefits of enhanced risk protections, including Kill Switch mechanisms, flow downstream to counter-parties both at the Exchange and at other options exchanges, thereby increasing systemic protections as well. Additionally, because the Exchange will continue offer this optional risk tool to all Members, the Exchange believes that it will encourage liquidity generally and remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest. To the extent the Exchange's proposal provides Members with greater control over their quotes and orders, and allows them to remove quotes and cancel orders in an appropriate manner, then the proposal may encourage Members to provide liquidity on GEMX and thus contribute to fair and orderly markets in a manner that protects the public interest and protects investors.

As noted above, this optional risk tool will continue to be offered to all Members. The Exchange further represents that its proposal will continue to operate consistently with the firm quote obligations of a broker-dealer pursuant to Rule 602 of Regulation NMS and that the functionality is not mandatory. Specifically, any interest that is executable against a Member's orders or quotes that are received [23] by the Exchange, prior to the time the Kill Switch is processed by the System, will automatically execute at the price up to the Member's size. The Kill Switch message will be accepted by the System in the order of receipt in the queue and will be processed in that order so that interest that is already accepted into the System will be processed prior to the Kill Switch message. Messages sent to the System by the Kill Switch are processed in the order they are received by the matching engine, through the same queuing mechanism that a quote or order message is processed. The Exchange also notes that the latency profile of the GUI Kill Switch is comparable to the latency profile of killing interest through a message based Kill Switch from a Member's order entry port.

A Market Maker's obligation to provide two-sided quotes on a daily basis is not diminished by the removal of such quotes and/or orders by utilizing the Kill Switch. Market Makers that utilize Kill Switch will not be relieved of the obligation to provide intra-day quotes pursuant to Options 2, Section 5(e), nor will it prohibit the Exchange from taking disciplinary action against a Market Maker for failing to meet its quoting obligations each trading day.

The proposed changes will also permit Clearing Members that clear transactions on a Member's behalf

[16] Members may not cancel orders and quotes by symbol using the GUI Kill Switch, similar to how orders may not be cancelled by symbol through the port Kill Switch today. Also similar to the port Kill Switch, Opening Sweeps will be cancelled upon initiating the GUI Kill Switch. Lastly, all auction orders and responses other than PIM orders/responses will similarly be cancelled. *See supra* note 5.

[17] As noted above, NOM Chapter VI, Sec. 6(d) has similar terminology in its Kill Switch rule. *See supra* note 9. Furthermore, the proposed GUI Kill Switch is functionally similar to NOM's Kill Switch in that both are offered through a separate graphical user interface and have similar features, including the ability for members to apply Kill Switch for certain identifiers on a user or group level.

[18] As an example of the GUI Kill Switch, assume a Market Maker is configured to trade on ISE and GEMX in badges 123A, 123B, and 123C, with pre-defined settings that include all three badges as one group to which the GUI Kill Switch will apply. The Market Maker could then submit a GUI Kill Switch request to restrict their quote activity for the pre-defined group, resulting in the cancellation of all existing quotes and restriction of additional quotes associated with badges 123A, 123B, and 123C across both ISE and GEMX. The same Market Maker could instead opt to submit a GUI Kill Switch request for only badge 123A to cancel all existing quotes and restrict entry of additional quotes for that individual badge. The proposed functionality therefore allows the Member to have more optionality as compared to the existing mechanism.

[19] Identical to re-entry for the port Kill Switch, Members must directly and verbally contact the Exchange to request the re-set if they initiate the GUI Kill Switch. *See supra* note 6 with accompanying text.

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(5).

[22] *See, e.g.,* Securities Exchange Act Release Nos. 69077 (March 8, 2013), 78 FR 18083 (March 25, 2013) (Proposing Release) at 18090–91; and 73639 (November 19, 2014), 79 FR 72251 (December 5, 2014) (Adopting Release) at 72253 (highlighting that quality standards, testing and improved error response mechanisms are among the issues needing very thoughtful and focused attention in today's securities markets).

[23] The time of receipt for an order or quote is the time such message is processed by the Exchange's order book.

pursuant to a Letter of Guarantee [24] to receive information regarding the Member's re-entry into the System after the Member initiates the GUI Kill Switch, and makes the verbal request to the Exchange for re-entry pursuant to Options 3, Section 17(a). As is the case today with the port Kill Switch, because such Clearing Members guarantee all transactions on behalf of that Member and therefore bear the risk associated with those transactions, the Exchange believes that it is appropriate for the Clearing Member to receive information regarding re-entry into the System after quotes and/or orders are cancelled as a result of the GUI Kill Switch, should the Clearing Member request such notification. This information may help provide Clearing Members with greater control and flexibility in managing the risk associated with the Member's activity.

The Exchange's proposal also extends the cross-market feature available today through the port Kill Switch to the proposed GUI Kill Switch. The Exchange notes that issues that would prompt a Member to submit a Kill Switch request are normally not confined to a member's activity on a single exchange. Accordingly, the Exchange believes that offering both the port and GUI Kill Switch protections on a cross-market basis would help Members to more effectively manage their risk when trading on multiple markets, and reduce disruptive trading events to the benefit of all members and investors. For the same reasons, the Exchange already offers other cross market risk protections pursuant to the Market Wide Risk Protection (''MWRP'') [25] as well as for market maker quotes, both of which can be applied across GEMX and ISE similar to the port and GUI Kill Switch.[26] Like MWRP and the cross-market protections for market maker quotes, the Exchange ported over the Kill Switch's cross-market feature from the Exchange's previous trading system with minimal modifications to minimize the impact to Members that were already familiar with the existing risk management tools.

Lastly, the Exchange believes that the proposed changes to add greater specificity with respect to how the port Kill Switch currently operates (*i.e.,* that a Kill Switch request sent through FIX, OTTO, or Precise will result in the cancellation of all existing orders, and restrict entry of additional orders for the requested Identifier(s) on a user level on GEMX, or across both GEMX and ISE, in either case as set by the Member) will promote greater transparency around the existing Kill Switch, and will serve to better align the Exchange's rules with current System functionality, to the benefit of investors and the public interest.

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 proposal does not impose an undue burden on intramarket competition because all Members may avail themselves of the Kill Switch. The Kill Switch risk protection is optional. The proposed rule change to expand this risk protection to encompass quote cancellation and restriction will further protect Members in the event the Member is suffering from a systems issue or from the occurrence of unusual or unexpected market activity that would require them to withdraw from the market in order to protect investors. As discussed above, the proposed GUI Kill Switch, like the existing port Kill Switch, would be offered cross-market to Members that want to be protected from inadvertent exposure to excessive risk when trading on both GEMX and ISE. The Exchange does not believe that permitting this functionality to be cross-market will impose any undue burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the target of the cross-market feature is to reduce risk for Members that trade on GEMX and ISE. As noted above, issues that would prompt a Member to submit a Kill Switch request are normally not confined to a Member's activity on a single exchange, so the Exchange believes that having the ability to manage risk across more than one market will ultimately be beneficial by providing Members with greater control over their quotes and orders, which may reduce disruptive trading events to the benefit of all investors and the public interest. Finally, the Exchange notes other exchanges, including the Exchange's affiliated options markets, similarly offer Kill Switch protections for both quotes and orders.[27]

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 [28] and subparagraph (f)(6) of Rule 19b–4 thereunder.[29]

A proposed rule change filed under Rule 19b–4(f)(6) [30] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[31] the Commission may 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. According to the Exchange, waiver of the operative delay is consistent with the protection of investors and the public interest because it would provide Members with greater control over their quotes and orders, which may reduce disruptive trading events to the benefit of all investors and the public interest. The Exchange notes that similar kill switch protections are available on other options exchanges and that the Commission has previously approved similar cross market risk protections,[32] and that as such, the proposed rule change does not raise any new, unique or substantive issues. The Commission

[24] A Letter of Guarantee obligates the issuing Clearing Member to accept financial responsibilities for all Exchange transactions made by the guaranteed Member. *See* Options 6, Section 4(a) and (b).

[25] *See* Options 3, Section 15(b)(1)(D).

[26] *See* Options 3, Section 15(b)(3)(B)(vi).

[27] The proposed GUI Kill Switch protections are similar to those available on its affiliated options markets Nasdaq BX (''BX''), NOM, and Nasdaq Phlx (''Phlx''), except BX, NOM, and Phlx Kill Switches do not apply cross-market to other affiliated exchanges. As discussed above, the proposed GUI Kill Switch may apply across GEMX and ISE, if set by the Exchange member. *See* BX Chapter VI, Section 6(d); NOM Chapter VI, Section 6(d); and Phlx Rule 1019(b). *See also* CBOE Exchange Rule 5.34(c)(7) and BOX Options Exchange Rule 7280(b) for other options exchanges that offer Kill Switch protections for quotes and orders.

[28] 15 U.S.C. 78s(b)(3)(A)(iii).

[29] 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 requested that the Commission waive the pre-filing requirement. The Commission hereby waives that requirement.

[30] 17 CFR 240.19b–4(f)(6).

[31] 17 CFR 240.19b–4(f)(6)(iii).

[32] *See supra* notes 25–27 and accompanying text.

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.[33]

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–GEMX–2019–15 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–GEMX–2019–15. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet 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–GEMX–2019–15 and should be submitted on or before November 25, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–23975 Filed 11–1–19; 8:45 am]

BILLING CODE 8011–01–P

[33] 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).

[34] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87414; File No. SR–MRX–2019–22]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Options 3, Section 17, the Exchange's Kill Switch Risk Protection

October 29, 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 October 15, 2019, Nasdaq MRX, LLC (''MRX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Options 3, Section 17, which sets forth the Exchange's optional Kill Switch risk protection.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqmrx.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 expand the optional Kill Switch risk protection the Exchange offers to Members today to allow cancellation and restriction of quotes, orders, or both. This new functionality will be offered alongside the existing port Kill Switch (as defined below), which currently allows Members to cancel and restrict only their orders. The Exchange also proposes to amend its rules to add more detail on how the port Kill Switch operates today. As discussed further below, no functional changes to the existing port Kill Switch functionality are being contemplated by this rule change; rather, the Exchange is providing more detailed information on the port Kill Switch so that the rule is more aligned with the current operation of existing functionality.

Port Kill Switch

Today, Kill Switch provides Members with a risk management tool for immediate control of their order activity. Specifically as set forth in Options 3, Section 17(a), Kill Switch enables Members to initiate a message [3] to the System [4] to promptly cancel orders and restrict entry of new orders

[3] Today, Members are able to send a message to the Exchange to initiate the Kill Switch. A Kill Switch message may be sent through the Exchange order entry ports FIX or OTTO (hereinafter, referred to as ''port Kill Switch'').

[4] The term ''System'' means the electronic system operated by the Exchange that receives and disseminates quotes, executes orders and reports transactions. *See* Options 1, Section 1(a)(48).

until re-entry has been enabled. Members may submit a request to the System to cancel orders for that Member. The System will send an automated message to the Member when a Kill Switch request has been processed by the Exchange's System.

If orders are cancelled by the Member utilizing the Kill Switch, it will result in the removal of all orders for the Member.[5] The Member is unable to enter additional orders until the Member has made a verbal request to the Exchange and Exchange staff has set a re-entry indicator to enable re-entry.[6] Once enabled for re-entry, the System will send a Re-entry Notification Message to the Member. The applicable Clearing Member for that Member will also be notified of the re-entry into the System after orders are cancelled as a result of the Kill Switch, provided the Clearing Member has requested to receive such notification.

The Exchange now proposes to provide additional detail regarding the port Kill Switch described above to better align the Rule with existing system functionality. The Exchange proposes to clarify that Members may submit a Kill Switch request to the System through FIX or OTTO for the Member's requested identifier (*i.e.,* badge[7] or mnemonic[8]) (''Identifier'') on a user level (*i.e.,* by individual badge or mnemonic).[9] As such, Members using the port Kill Switch today may elect to cancel all existing orders and restrict entry of additional orders by individual badge/mnemonic (*i.e.,* Identifier).[10]

While the current rule text does not specifically provide for the ability to cancel and restrict orders by individual Identifier(s), the existing port Kill Switch functionality operates in this manner today. Accordingly, the Exchange proposes to replace the existing language in section (a)(1) with the following to make clear how the System operates today: ''A Member may submit a request to the System through FIX or OTTO to cancel all existing orders and restrict entry of additional orders for the requested Identifier(s) on a user level on the Exchange.''

As noted above, the Exchange is not proposing any functional modifications to the existing port Kill Switch; rather, all of the changes proposed above are to provide additional specificity as to how the port Kill Switch operates today for greater consistency between the rule text and the operation of the System. Lastly, the Exchange proposes to delete the last sentence of (a)(1), which is redundant with the re-entry provisions already set forth in the Rule.[11]

GUI Kill Switch

The Exchange also proposes to add new functionality that would enhance the current Kill Switch risk protection for orders to apply to both orders and quotes.[12] The Exchange will provide this enhancement through a separate graphical user interface (hereinafter, ''GUI Kill Switch'') as an alternative way for Members to manage their trading activity.[13] As discussed below, the new GUI Kill Switch will be functionally similar to the existing port Kill Switch, with the most notable difference being the added ability to cancel all existing quotes and block the entry of additional quotes. For instance, similar to the port Kill Switch today, Members will be able to use the GUI Kill Switch for requested Identifier(s) on the Exchange. Accordingly, Options 3, Section 17 will be amended to reflect that the Exchange will offer the proposed GUI Kill Switch alongside the existing port Kill Switch. In particular, paragraph (a) will provide that Kill Switch would enable Members to initiate a message to the System to promptly cancel and restrict their quote and order activity on the Exchange, as further described in the Rule. The Exchange also proposes to specify that Members may submit a Kill Switch request to the System for certain Identifier(s) on either a user or group level. Permissible groups must reside within a single Member firm.[14]

As discussed above, while the proposed language in section (a) on applying Kill Switch for requested Identifier(s) on the Exchange is new, these features exist today with respect to the port Kill Switch. Accordingly, the proposed changes in (a) with respect to order cancellation and restriction clarify the current manner in which the port Kill Switch operates today, and also extends the rule to encompass the proposed GUI Kill Switch.

The Exchange further proposes to describe the new GUI Kill Switch functionality in new section (a)(2).[15] Specifically, the Exchange proposes to add the following: ''Alternatively, a Member may submit a request to the System through a graphical user interface to cancel all existing, and restrict entry of additional, quotes and/or orders for the requested Identifier(s) on either a user or group level on the Exchange.'' [16]

The Exchange believes that the proposed enhancement to the Kill Switch will offer Members an alternative means to control their exposure, through a separate interface which is not dependent on the integrity of the member's own systems, should the member experience a failure. Because the proposed enhancement will be provided through a separate user interface instead of one of the Exchange's order entry ports, the Exchange believes it would promote transparency in its Rules to separately define these alternative methods in (a)(1) and (a)(2). As noted above, the

[5] Members may not cancel orders by symbol. Of note, Opening Sweeps are also cancelled. An Opening Sweep is a Market Maker order submitted for execution against eligible interest in the system during the Opening Process pursuant to Options 3, Section 8(b)(1). *See* Options 3, Section 7(u). Consistent with current auction functionality, PIM auction orders and responses are not cancelled. PIM is the Exchange's price improvement mechanism. *See* Options 3, Section 13. Other auctions orders and responses are cancelled.

[6] The Member must directly and verbally contact the Exchange to request the re-set.

[7] A ''badge'' shall mean an account number, which may contain letters and/or numbers, assigned to Market Makers. A Market Maker account may be associated with multiple badges. *See* Options 1, Section 1(a)(4).

[8] A ''mnemonic'' shall mean an acronym comprised of letters and/or numbers assigned to Electronic Access Members. An Electronic Access Member account may be associated with multiple mnemonics. *See* Options 1, Section 1(a)(22).

[9] Using the port Kill Switch, Members are only able to cancel and restrict their order activity at the user level (*i.e.,* by individual Identifier). As discussed below, the new Kill Switch enhancement will offer Members the additional option of submitting requests at the user level or group level—in other words, by individual Identifier or for a group of Identifiers. *See, e.g.,* Nasdaq Options Market (''NOM'') Chapter VI, Sec. 6(d), which sets forth NOM's Kill Switch rule, for similar terminology related to Identifier.

[10] Thus, for example, an Electronic Access Member that is configured to trade on the Exchange in mnemonics ABCD1, ABCD2, and ABCD3 would submit a separate request for each mnemonic using the port Kill Switch, which would result in the cancellation of all existing orders and the restriction of additional orders associated with mnemonics ABCD1, ABCD2, and ABCD3 on the Exchange.

[11] *See* Options 3, Section 17(a)(2). As discussed below, this section will be renumbered as section (a)(3) under this proposal.

[12] As discussed more fully later in the filing, the proposed Kill Switch enhancement will also have additional features to allow Members to kill quotes and/or orders for requested Identifier(s) on either a user or group level.

[13] The GUI Kill Switch will be available to all Members through a web-based interface.

[14] For example, a permissible group could include all badges associated with a Market Maker. Member would be able to set up these groups beforehand to include all or some of the Identifiers associated with the Member firm so that a GUI Kill Switch request could apply to this pre-defined group.

[15] In light of adopting this new section, current (a)(2) will be renumbered as (a)(3).

[16] Members may not cancel orders and quotes by symbol using the GUI Kill Switch, similar to how orders may not be cancelled by symbol through the port Kill Switch today. Also similar to the port Kill Switch, Opening Sweeps will be cancelled upon initiating the GUI Kill Switch. Lastly, all auction orders and responses other than PIM orders/responses will similarly be cancelled. *See supra* note 5.

proposed enhancement is similar to the existing port Kill Switch that allows Members to control their order activity but has additional optionality, most significantly the ability to cancel and restrict quotes, orders, or both. Furthermore, Members can set up the GUI Kill Switch so they are able to control their quote and/or order activity for an individual Identifier or a group of Identifiers,[17] as compared to the port Kill Switch which is limited to individual Identifiers only.[18]

The re-entry provisions in section (a)(3) will also be amended throughout to reflect that the re-entry process after initiating the GUI Kill Switch will be identical to the current process for the port Kill Switch. Specifically, once a Member initiates either the port or GUI Kill Switch, the Member will be unable to enter additional orders, and/or quotes if pursuant to the GUI Kill Switch, for the affected Identifier(s) until the Member has made a verbal request to the Exchange and Exchange staff has set a re-entry indicator to enable re-entry.[19] Lastly, the Exchange proposes to make a related change in the last sentence of section (a)(3) to delete the reference to order cancellation, and also provide that the ''applicable Clearing Member will be notified of *such* re-entry . . .'' for better readability.

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, by enhancing the risk protections available to Members. The proposal promotes policy goals of the Commission which has highlighted the need for execution venues, exchange and non-exchange alike, to enhance risk protection tools and other mechanisms to decrease risk and increase stability.[22]

The proposed GUI Kill Switch, similar to the existing port Kill Switch, is designed to protect Members in the event the Member encounters a situation, like a systems issue, for which they would need to withdraw temporarily from the market. The individual Member firm benefits of enhanced risk protections, including Kill Switch mechanisms, flow downstream to counter-parties both at the Exchange and at other options exchanges, thereby increasing systemic protections as well. Additionally, because the Exchange will continue offer this optional risk tool to all Members, the Exchange believes that it will encourage liquidity generally and remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest. To the extent the Exchange's proposal provides Members with greater control over their quotes and orders, and allows them to remove quotes and cancel orders in an appropriate manner, then the proposal may encourage Members to provide liquidity on MRX and thus contribute to fair and orderly markets in a manner that protects the public interest and protects investors.

As noted above, this optional risk tool will continue to be offered to all Members. The Exchange further represents that its proposal will continue to operate consistently with the firm quote obligations of a broker-dealer pursuant to Rule 602 of Regulation NMS and that the functionality is not mandatory. Specifically, any interest that is executable against a Member's orders or quotes that are received[23] by the Exchange, prior to the time the Kill Switch is processed by the System, will automatically execute at the price up to the Member's size. The Kill Switch message will be accepted by the System in the order of receipt in the queue and will be processed in that order so that interest that is already accepted into the System will be processed prior to the Kill Switch message. Messages sent to the System by the Kill Switch are processed in the order they are received by the matching engine, through the same queuing mechanism that a quote or order message is processed. The Exchange also notes that the latency profile of the GUI Kill Switch is comparable to the latency profile of killing interest through a message based Kill Switch from a Member's order entry port.

A Market Maker's obligation to provide two-sided quotes on a daily basis is not diminished by the removal of such quotes and/or orders by utilizing the Kill Switch. Market Makers that utilize Kill Switch will not be relieved of the obligation to provide intra-day quotes pursuant to Options 2, Section 5(e), nor will it prohibit the Exchange from taking disciplinary action against a Market Maker for failing to meet its quoting obligations each trading day.

The proposed changes will also permit Clearing Members that clear transactions on a Member's behalf pursuant to a Letter of Guarantee[24] to receive information regarding the Member's re-entry into the System after the Member initiates the GUI Kill Switch, and makes the verbal request to the Exchange for re-entry pursuant to Options 3, Section 17(a). As is the case today with the port Kill Switch, because such Clearing Members guarantee all transactions on behalf of that Member and therefore bear the risk associated with those transactions, the Exchange believes that it is appropriate for the Clearing Member to receive information regarding re-entry into the System after quotes and/or orders are cancelled as a result of the GUI Kill Switch, should the Clearing Member request such notification. This information may help provide Clearing Members with greater control and flexibility in managing the risk associated with the Member's activity.

Lastly, the Exchange believes that the proposed changes to add greater specificity with respect to how the port Kill Switch currently operates (*i.e.,* that a Kill Switch request sent through FIX or OTTO will result in the cancellation

[17] As noted above, NOM Chapter VI, Sec. 6(d) has similar terminology in its Kill Switch rule. *See supra* note 9. Furthermore, the proposed GUI Kill Switch is functionally similar to NOM's Kill Switch in that both are offered through a separate graphical user interface and have similar features, including the ability for members to apply Kill Switch for certain identifiers on a user or group level.

[18] As an example of the GUI Kill Switch, assume a Market Maker is configured to trade on the Exchange in badges 123A, 123B, and 123C, with pre-defined settings that include all three badges as one group to which the GUI Kill Switch will apply. The Market Maker could then submit a GUI Kill Switch request to restrict their quote activity for the pre-defined group, resulting in the cancellation of all existing quotes and restriction of additional quotes associated with badges 123A, 123B, and 123C on the Exchange. The same Market Maker could instead opt to submit a GUI Kill Switch request for only badge 123A to cancel all existing quotes and restrict entry of additional quotes for that individual badge. The proposed functionality therefore allows the Member to have more optionality as compared to the existing mechanism.

[19] Identical to re-entry for the port Kill Switch, Members must directly and verbally contact the Exchange to request the re-set if they initiate the GUI Kill Switch. *See supra* note 6 with accompanying text.

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(5).

[22] *See, e.g.,* Securities Exchange Act Release Nos. 69077 (March 8, 2013), 78 FR 18083 (March 25, 2013) (Proposing Release) at 18090–91; and 73639 (November 19, 2014), 79 FR 72251 (December 5, 2014) (Adopting Release) at 72253 (highlighting that quality standards, testing and improved error response mechanisms are among the issues needing very thoughtful and focused attention in today's securities markets).

[23] The time of receipt for an order or quote is the time such message is processed by the Exchange's order book.

[24] A Letter of Guarantee obligates the issuing Clearing Member to accept financial responsibilities for all Exchange transactions made by the guaranteed Member. *See* Options 6, Section 4(a) and (b).

of all existing orders, and restrict entry of additional orders for the requested Identifier(s) on a user level on the Exchange) will promote greater transparency around the existing Kill Switch, and will serve to better align the Exchange's rules with current System functionality, to the benefit of investors and the public interest.

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 proposal does not impose an undue burden on intramarket competition because all Members may avail themselves of the Kill Switch. The Kill Switch risk protection is optional. The proposed rule change to expand this risk protection to encompass quote cancellation and restriction will further protect Members in the event the Member is suffering from a systems issue or from the occurrence of unusual or unexpected market activity that would require them to withdraw from the market in order to protect investors. The Exchange notes other exchanges, including the Exchange's affiliated options markets, similarly offer Kill Switch protections for both quotes and orders.[25]

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[26] and subparagraph (f)(6) of Rule 19b–4 thereunder.[27]

A proposed rule change filed under Rule 19b–4(f)(6)[28] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[29] the Commission may 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. According to the Exchange, waiver of the operative delay is consistent with the protection of investors and the public interest because it would provide Members with greater control over their quotes and orders, which may reduce disruptive trading events to the benefit of all investors and the public interest. The Exchange notes that similar kill switch protections are available on other options exchanges,[30] and as such, the proposed rule change does not raise any new, unique or substantive issues. 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.[31]

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:

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- 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–MRX–2019–22 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–MRX–2019–22. 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–MRX–2019–22 and should be submitted on or before November 25, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–23976 Filed 11–1–19; 8:45 am]

BILLING CODE 8011–01–P

[25] The proposed GUI Kill Switch protections are similar to those available on its affiliated options markets Nasdaq BX (''BX''), NOM, and Nasdaq Phlx (''Phlx''). *See* BX Chapter VI, Section 6(d); NOM Chapter VI, Section 6(d); and Phlx Rule 1019(b). *See also* CBOE Exchange Rule 5.34(c)(7) and BOX Options Exchange Rule 7280(b) for other options exchanges that offer Kill Switch protections for quotes and orders.

[26] 15 U.S.C. 78s(b)(3)(A)(iii).

[27] 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 requested that the Commission waive the pre-filing requirement. The Commission hereby waives that requirement.

[28] 17 CFR 240.19b–4(f)(6).

[29] 17 CFR 240.19b–4(f)(6)(iii).

[30] *See supra* notes 25.

[31] 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).

[32] 17 CFR 200.30–3(a)(12).

SURFACE TRANSPORTATION BOARD

[Docket No. WB19–58]

Release of Waybill Data

The Surface Transportation Board (Board) has received a request Neville Peterson LLP on behalf of Trinity Industries, Inc. (WB19–58—10/29/19) for permission to use select data from the Board's 2018 Masked Carload Waybill Sample. A copy of this request may be obtained from the Board's website under docket no. WB19–58.

The waybill sample contains confidential railroad and shipper data; therefore, if any parties object to these requests, they should file their objections with the Director of the Board's Office of Economics within 14 calendar days of the date of this notice. The rules for release of waybill data are codified at 49 CFR 1244.9.

Contact: Alexander Dusenberry, (202) 245–0319.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2019–24062 Filed 11–1–19; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Intent; Environmental Impact Statement: I–285 Top End Express Lanes in Cobb, Fulton, and DeKalb Counties, Georgia

AGENCY: Federal Highway Administration, DOT.

ACTION: Notice of intent to prepare an Environmental Impact Statement (EIS).

SUMMARY: The FHWA is issuing this notice to advise the public that an Environmental Impact Statement (EIS) will be prepared for a proposed project on I–285 in Cobb, Fulton, and DeKalb counties, Georgia. The Georgia Department of Transportation (GDOT) is sponsoring the project to address the substantial congestion in this corridor that results in unreliable travel times and diminished accessibility to employment and activity centers.

FOR FURTHER INFORMATION CONTACT:

Moises Marrero, Division Administrator, Federal Highway Administration, 61 Forsyth Street, Suite 17T100, Atlanta, Georgia 30303, Telephone: (404) 562–3630; email: *Moises.Marrero@dot.gov.*

Tim Matthews, GDOT Project Manager, Georgia Department of Transportation, One Georgia Center, 600 West Peachtree Street NW, 25th Floor, Atlanta, Georgia 30308. Telephone: (404) 631–1713; email: *tmatthews@dot.ga.gov.*

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the Georgia Department of Transportation (GDOT), will prepare an EIS for proposed express lanes across the top end of I–285 roughly between the I–75 and I–85 corridors. The FHWA intends to issue a combined Final EIS/ROD document pursuant to 23 CFR 771.124, unless FHWA determines the regulatory criteria or practicability considerations preclude issuance of a combined document.

The proposed I–285 Top End Express Lanes project is being developed to improve mobility and offer predictable travel times along the I–285 corridor and is a product of studies and recommendations included in the Atlanta Region Managed Lanes Systems Plan and Managed Lanes Implementation Plan. The total project length would be approximately 28 miles. An evaluation under Section 4(f) of the DOT Act of 1966 may also be required due to the potential for impacts to public recreational areas and resources eligible for the National Register of Historic Places.

A study corridor large enough to incorporate detailed studies for the full range of alternatives to be considered for the project will be evaluated. The EIS will be prepared in accordance with the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 *et seq.*), 23 U.S.C. 139, Council on Environmental Quality (CEQ) regulations implementing NEPA (40 CFR 1500–1508), FHWA regulations implementing NEPA (23 CFR 771.101–771.139) and other applicable Federal, State, and local governmental laws and regulations. In addition, the EIS will fulfill the applicable provisions of the Safe Accountable Flexible Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU); Moving Ahead for Progress in the 21st Century (MAP–21); and Fixing America's Surface Transportation (FAST) Act.

Ongoing and continuing agency coordination is outlined in the project Agency Coordination Plan (ACP). Additional information, including the project Need and Purpose, the ACP, and the Public Involvement Plan can be found on the project website at *https://majormobilityga.com/projects/topend/.* These documents are available for public and agency review and comment. This website also includes project schedules and information about past and upcoming meetings.

Public involvement is also a critical component of NEPA project development. To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, public outreach and involvement will continue through project development. Comments and suggestions are invited from all interested parties. A public hearing will be held after the completion of the Draft EIS, and the EIS will be made available for review by federal and state resource agencies and the public.

(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. 315; 49 CFR 1.48.

Issued on: October 29, 2019.

Moises Marrero,

Georgia Division Administrator, Federal Highway Administration.

[FR Doc. 2019–24032 Filed 11–1–19; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice To Rescind the Notice of Intent To Prepare a Limited Scope Supplemental Environmental Impact Statement: Interstate 55 Interchange in Shelby County, Tennessee

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice to rescind the Notice of Intent to prepare a Limited Scope Supplemental Environmental Impact Statement.

SUMMARY: The FHWA is issuing this notice to advise the public that the Notice of Intent (NOI) published on August 31, 2015, to prepare a Limited Scope Supplemental Environmental Impact Statement (LSSEIS) for the proposed improvements to the Interstate 55 (I–55) interchange at E.H. Crump Boulevard in the City of Memphis, Shelby County, Tennessee, is being rescinded.

FOR FURTHER INFORMATION CONTACT: Ms. Theresa Claxton, Program Development Team Leader, Federal Highway Administration, Tennessee Division Office, 404 BNA Drive, Suite 508, Nashville, TN 37217, Telephone: 615–781–5770.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the Tennessee Department of Transportation (TDOT), is rescinding

the NOI to prepare an LSSEIS for proposed improvements to the I–55 interchange at E.H. Crump Boulevard in the City of Memphis, Shelby County, Tennessee. The Selected Alternative consists of replacing the existing cloverleaf interchange with a new interchange configuration that will provide through lanes for mainline I–55 traffic, eliminating the need for interstate traffic to use single-lane, low speed ramps to continue on I–55. A new multi-lane roundabout interchange will be constructed, replacing the existing cloverleaf interchange, providing improved access to and from I–55 and existing local roadways.

The Final Environmental Impact Statement (FEIS) was approved on June 28, 2011. On January 25, 2012, FHWA issued a Record of Decision (ROD) identifying the Selected Alternative and the reasons for its selection. Following the issuance of the ROD, TDOT determined that a total closure of the I–55 Bridge over the Mississippi River (Memphis-Arkansas Bridge) for up to 9 months may be necessary. A Reevaluation of the FEIS was initiated to further explore the proposed construction phasing of the project. Through this process, TDOT, in coordination with FHWA, determined that the proposed construction phasing could result in potentially significant impacts not previously assessed and disclosed in the EIS. Therefore, TDOT concluded the Reevaluation with the determination that a LSSEIS should be undertaken. The NOI to develop the LSSEIS was published on August 31, 2015.

Since the publication of the NOI, TDOT has taken several major steps to advance the project towards construction including the decision to not pursue the total closure of the I–55 Bridge for up to 9 months during construction of the project. Because the previously proposed option for a total closure of the I–55 Bridge for up to 9 months was the primary reason for developing a LSSEIS, TDOT, in coordination with FHWA has determined that an LSSEIS is no longer warranted and that a Reevaluation of the FEIS will now be prepared. Therefore, the August 31, 2015 NOI is being rescinded.

The Reevaluation will fully evaluate impacts to humans and to the natural environment and will evaluate changes to the proposed project since the issuance of the ROD.

Comments and questions concerning the proposed action should be directed to the FHWA contact person at the address provided above.

Issued on: October 29, 2019.

Pamela M. Kordenbrock,

Division Administrator, Nashville, TN.

[FR Doc. 2019–24031 Filed 11–1–19; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0184]

Request for Comments on the Approval of a Previously Approved Information Collection: United States Merchant Marine Academy (USMMA) Alumni Survey

AGENCY: Maritime Administration, DOT.

ACTION: Notice and request for comments.

SUMMARY: The Maritime Administration (MARAD) invites public comments on our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The purpose of the collection is to conduct alumni survey to document student perceptions about education received at the U.S. Merchant Marine Academy (USMMA). The results from the survey will not be used for any type of forecasting or projecting. The results will be tabulated and documented as indirect evidence for accreditation purposes. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Comments must be submitted on or before January 3, 2020.

ADDRESSES: You may submit comments [identified by Docket No. MARAD–2019–0028] through one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Search using the above DOT docket number and follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.

Mail or Hand Delivery: Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Dr. John R. Ballard, (516) 726–5833, U.S. Merchant Marine Academy, Kings Point, NY 11024.

SUPPLEMENTARY INFORMATION:

Title: U.S. Merchant Marine Academy Alumni Survey.

OMB Control Number: 2133–0542.

Type of Request: Renewal of a previously approved collection.

Abstract: The United States Merchant Marine Academy is an accredited federal service academy that confers BS and MS degrees. The Academy is expected to assess its educational outcomes and report those findings to its Regional Accreditation authority in order to maintain the institution's degree granting status. Periodic survey of alumni cohorts and analysis of the data gathered is a routine higher education assessment practice in the United States.

Respondents: Respondents are graduates of the U.S. Merchant Marine Academy.

Affected Public: U.S. Merchant Marine Academy Graduates.

Estimated Number of Respondents: 600.

Estimated Number of Responses: 600.

Estimated Hours per Response: .25 Hrs.

Annual Estimated Total Annual Burden Hours: 150.

Frequency of Response: Annually.

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.93.)

* * * * *

Dated: October 30, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–24022 Filed 11–1–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0182]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel LATITUDE (Sailboat); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the

Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 4, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0182 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0182 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0182, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel LATITUDE is:

—*Intended Commercial Use of Vessel:* ''Light charter (4 to 8 weeks/year) with full time U.S. crew. In the U.S. Virgin Islands in Winter and the U.S. East Coast (Maine, Massachusetts, Rhode Island) in Summer''

—*Geographic Region Including Base of Operations:* ''Maine, Massachusetts, Rhode Island'' (Base of Operations: Newport, RI)

—*Vessel Length and Type:* 64′ sailboat

The complete application is available for review identified in the DOT docket as MARAD–2019–0182 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.*, keyword search MARAD–2019–0182 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.

* * * * *

Dated: October 30, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–24017 Filed 11–1–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0175]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel KONA STAR (Motor Vessel); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 4, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0175 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0175 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0175, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel KONA STAR is:

—*Intended Commercial Use of Vessel:* ''Whale watching, offshore Friday night fireworks observation, day cruises and special occasions.''
—*Geographic Region Including Base of Operations:* ''Hawaii'' (Base of Operations: Honolulu, HI)
—*Vessel Length and Type:* 45′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2019–0175 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2019–0175 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.

* * * * *

Dated: October 30, 2019.

T. Mitchell Hudson, Jr.

Secretary, Maritime Administration.

[FR Doc. 2019–24016 Filed 11–1–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0176]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel OLIMPO (Motor Vessel); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 4, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0176 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0176 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0176, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m.,

Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel OLIMPO is:

—*Intended Commercial Use of Vessel:* ''Chartering of passengers within six pack license restrictions. No cargo, fishing, towing, dredging, salvage or other commercial activity will be carried out by the vessel.''

—*Geographic Region Including Base of Operations:* ''Puerto Rico'' (Base of Operations: Puerto Del Ray Marina, PR)

—*Vessel Length and Type:* 63′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2019–0176 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2019–0176 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.

* * * * *

Dated: October 30, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–24021 Filed 11–1–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0174]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel IMAGINE THAT (Motor Vessel); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 4, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0174 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0174 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0174, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and

specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel IMAGINE THAT is:

—*Intended Commercial Use of Vessel:* ''Coastwise yacht time charter as an uninspected passenger vessel.''

—*Geographic Region Including Base of Operations:* ''New York, New Jersey, Massachusetts and Rhode Island; however, for informational purposes, the specifically intended areas are the Hudson River from the southernmost point to Albany NY. From Jersey City NJ south to Atlantic City in the coastal waters. The length of the East River, Harlem River and the complete Long Island sound out to Atlantic oceans and as Far East as Nantucket.'' (Base of Operations: Jersey City, NJ)

—*Vessel Length and Type:* 56′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2019–0174 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2019–0174 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.

* * * * *

Dated: October 30, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–24015 Filed 11–1–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0181]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel MADEMOISELLE CANDICE (Pontoon Boat); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 4, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0181 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0181 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0181, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information

provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel MADEMOISELLE CANDICE is:

—*Intended Commercial Use of Vessel:* ''Harbor Tours''

—*Geographic Region Including Base of Operations:* ''California'' (Base of Operations: Newport Beach Harbor, CA)

—*VEssel Length and Type:* 30′ pontoon boat

The complete application is available for review identified in the DOT docket as MARAD–2019–0181 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov*, keyword search MARAD–2019–0181 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

Dated: October 30, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–24019 Filed 11–1–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0177]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel MAGRATHEA (Sailing Vessel); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 4, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0177 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0177 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0177, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel MAGRATHEA is:

—*Intended Commercial Use of Vessel:* ''Applicant intends to operate MAGRATHEA as a private yacht and on occasion make the vessel available as a mid-sized luxury charter vessel.

MAGRATHEA will provide a safe platform from which guests may experience multi day voyages and the exceptional experience of living and sailing on an Oyster yacht.''

—*Geographic Region Including Base of Operations:* ''Rhode Island, Connecticut, Massachusetts'' (Base of Operations: Newport, RI)

—*Vessel Length and TYPE:* 72′ sailing vessel

The complete application is available for review identified in the DOT docket as MARAD–2019–0177 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov*, keyword search MARAD–2019–0177 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: October 30, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–24020 Filed 11–1–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0179]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel LIBERTY (Motor Vessel); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 4, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0179 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0179 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0179, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel LIBERTY is:

—*Intended Commercial Use of Vessel:* ''½ day, full day, and overnight sailing charters to view both the coast of Maine in the summer and Florida in the winter. If needed, we can provide a brochure for reference. If possible, we request a rush on our application. Thank you in advance for your help.''

— *Geographic Region Including Base Of Operations:* ''Maine, Florida'' (Base of Operations: Saco, ME)

—*Vessel Length and Type:* 44′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2019–0179 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2019–0179 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: October 30, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–24018 Filed 11–1–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0178]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel ENDLESS ROMANCE (Motor Vessel); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 4, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0178 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0178 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0178, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel ENDLESS ROMANCE is:

—*Intended Commercial Use of Vessel:* ''Vessel will engage in high end limited capacity charter for sunset cruises, private events, bay tours.''

—*Geographic Region Including Base of Operations:* ''California'' (Base of Operations: San Diego, CA)

—*Vessel Length and Type:* 78′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2019–0178 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses

U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2019–0178 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Dated: October 30, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–24013 Filed 11–1–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0180]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel HURRICANE (Motor Vessel); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 4, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0180 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0180 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–019–0180, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel HURRICANE is:

—*Intended Commercial Use of Vessel:* Bareboat charter for 12 clients in season charter 4–6 charters per month 3–4 months

—*Geographic Region Including Base of Operations:* ''Illinois'' (Base of Operations: Chicago, IL)

—*Vessel Length and Type:* 65′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2019–0180 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your

comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2019–0180 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.

Dated: October 30, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–24014 Filed 11–1–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Revision; Submission for OMB Review; Regulation E—Electronic Fund Transfer Act and Regulation Z—Truth in Lending Act

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to take this opportunity to comment on a continuing information collection as required by the Paperwork Reduction Act of 1995 (PRA).

An agency may not conduct or sponsor, and respondents are not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning revisions to the information collections titled ''Regulation E—Electronic Fund Transfer Act'' and ''Regulation Z—Truth in Lending Act.'' The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be submitted on or before December 4, 2019.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, 1557–NEW, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–NEW'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Additionally, please send a copy of your comments by mail to: OCC Desk Officer, 1557–NEW, U.S. Office of Management and Budget, 725 17th Street NW, #10235, Washington, DC 20503 or by email to *oira_submission@omb.eop.gov.*

You may review comments and other related materials that pertain to this information collection [1] following the close of the 30-day comment period for this notice by any of the following methods:

- *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Click on the ''Information Collection Review'' tab. Underneath the ''Currently under Review'' section heading, from the drop-down menu select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–NEW'' or ''Regulation E—Electronic Fund Transfer Act'' and ''Regulation Z—Truth in Lending Act.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.
- *Viewing Comments Personally:* You may personally inspect comments at the OCC, 400 7th Street SW, Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect comments.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

[1] On May 20, 2019, the OCC published a 60-day notice for this information collection, 84 FR 22931.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or disclose information to a third party. The OCC asks that it approve the information collection contained in this notice.

Title: Regulation E—Electronic Fund Transfer Act and Regulation Z—Truth in Lending Act.

OMB Control Nos.: 1557–NEW.[2]

Type of Review: Regular review.

Description: The Electronic Fund Transfer Act (EFTA)[3] and Regulation E[4] require disclosure of basic terms, costs, and rights relating to electronic fund transfer services debiting or crediting a consumer's account. The Truth in Lending Act (TILA)[5] and Regulation Z[6] require that the costs and terms of credit be disclosed to consumers.

The Prepaid Accounts final rules issued by the Consumer Financial Protection Bureau (CFPB)[7] require financial institutions to make available to consumers disclosures before a consumer acquires a prepaid account. This notice outlines the requirements of the 2016 rule as amended by the 2018 rule.

Regulation E

Under 12 CFR 1005.18(b), a financial institution is required to make available a short form and a long form disclosure before the consumer acquires a prepaid account, subject to certain exceptions. Most of the content required in the long form disclosure is already provided in prepaid account agreements. Section 1005.18(f)(3) requires that certain disclosures be made on the actual prepaid account access device, including the name of the financial institution and the URL of its website, and a telephone number the consumer may use to contact the financial institution about the prepaid account.

Financial institutions offering prepaid accounts that qualify for the retail location exception in § 1005.18(b)(1)(ii) may meet the requirement of providing the long form disclosure after acquisition by allowing the long form disclosure to be delivered electronically, without receiving consumer consent under the E-Sign Act,[8] if the disclosure is not provided inside the prepaid account packaging material and the financial institution is not otherwise mailing or delivering to the consumer written account-related communications within 30 days of obtaining the consumer's contact information. If a financial institution provides pre-acquisition disclosures in writing and a consumer subsequently completes the acquisition process online or by telephone, the financial institution is not required to provide the disclosures again either electronically or orally. Financial institutions that disclose additional fee types with three or more fee variations may consolidate them into two categories and disclose them on the short form.

Section 1005.18(b)(9)(i)(C) includes a requirement that a financial institution provide pre-acquisition disclosures in a foreign language if the financial institution provides a means for the consumer to acquire a prepaid account by telephone or electronically principally in that foreign language. That requirement is not applicable to payroll card accounts and government benefit accounts where the foreign language is offered by telephone only via a real-time language interpretation service provided by a third party or directly by an employer or government agency on an informal or ad hoc basis as an accommodation to prospective payroll card account or government benefit account recipients.

Section 1005.18(c)(1) requires financial institutions to furnish periodic statements to the consumer unless the provider uses the alternative method of compliance. Under this alternative method, the periodic statements must include: (1) A telephone number that the consumer may call to obtain the account balance; (2) the means by which the consumer can obtain an electronic account history, such as the address of a website; and (3) a summary of the consumer's right to receive a written account history upon request (in place of the summary of the right to receive a periodic statement required by § 1005.7(b)(6)), including a telephone number to call to request a history. Section 1005.18(c)(5) requires that financial institutions disclose to consumers a summary total of the amount of all fees assessed against the consumer's prepaid account for both the prior month as well as the calendar year to date. This information must be disclosed on any periodic statement and any electronic or written history of account transactions provided or made available by the financial institution.

The limited liability and error provisions of Regulation E now extend to all prepaid accounts, except those that have not successfully completed the financial institution's consumer identification and verification process. With regard to accounts where the consumer's identity is later verified, financial institutions are not required to resolve errors and limit liability for disputed transactions occurring prior to the verification. For accounts in programs where there is no verification process, financial institutions must either explain in their initial disclosures their error resolution process and limitations on consumers' liability for unauthorized transfers, or explain that there are no such protections, and that such financial institutions comply with the process (if any) that they disclose.[9]

Pursuant to § 1005.18(h)(1), except as provided in § 1005.18(h)(2) and (3), the effective date for the Prepaid Accounts Rules is April 1, 2019. If, as a result of § 1005.18(h)(1), a financial institution changes the terms and conditions of a prepaid account, such that a change-in-terms notice would have been required under § 1005.8(a) or § 1005.18(f)(2) for existing customers, the financial institution must notify consumers with accounts acquired before April 1, 2019, at least 21 days in advance of the change becoming effective, provided the financial institution has the consumer's contact information. If the financial institution obtains the consumer's contact information fewer than 30 days in advance of the change becoming effective or after it has become effective, the financial institution is permitted instead to provide notice of the change within 30 days of obtaining the consumer's contact information.

If a financial institution has received an E-Sign consent from the consumer, the financial institution may notify the consumer electronically. Otherwise, if a financial institution mails or delivers written communications to the consumer within the applicable time period, that financial institution must send a notice in physical form. If the financial institution will not mail or deliver communications to the consumer within the applicable time period, then the financial institution may notify the consumer in electronic form without regard to the consumer

[2] Regulations E and Z are currently covered by OMB Control No. 1557–0176, which also covers other consumer regulations. The OCC is requesting a new control number for this portion of Regulations E and Z only.

[3] 15 U.S.C. 1693 *et seq.*

[4] 12 CFR part 1005.

[5] 15 U.S.C. 1601 *et seq.*

[6] 12 CFR part 1026.

[7] 81 FR 83934 (November 22, 2016) and 83 FR 6364 (February 13, 2018).

[8] Electronic Signatures in Global and National Commerce Act (E-Sign Act) (15 U.S.C. 7001 *et seq.*).

[9] 12 CFR 1005.18(e)(1) and (2).

notice and consent requirements of section 101(c) of the E-Sign Act.

Section 1005.18(h)(2)(ii) requires that financial institutions notify any consumer, who acquires a prepaid account after the effective date specified in packaging printed prior to the effective date, of any changes as a result of § 1005.18(h)(1) taking effect that would have caused a change-in-terms notice to be required under § 1005.8(a) or § 1005.18(f)(2) for existing customers within 30 days of acquiring the customer's contact information. In addition, financial institutions must mail or deliver updated initial disclosures pursuant to §§ 1005.7 and 1005.18(f)(1) within 30 days of obtaining the consumer's contact information. Those financial institutions that are affected should not incur significant costs associated with notifying consumers and providing updated initial disclosures. Consumers who have consented to electronic communication may receive the notices and updated disclosures electronically, at a minimal cost to financial institutions. Those consumers who cannot be contacted electronically may receive the notices and updated initial disclosures together with another scheduled mailing within the 30-day time period. Any remaining consumers who are not scheduled to receive mailings may be notified without regard to the consumer notice and consent requirements of section 101(c) of the E-Sign Act.

Section 1005.19(b) requires certain issuers to submit to the CFPB, on a rolling basis, short form disclosures, prepaid account agreements (including fee schedules) that are offered, amended, or withdrawn. Prepaid account issuers are permitted to delay submitting a change in the list of names of other relevant parties to a particular prepaid account agreement until the earlier of such time as the issuer is otherwise submitting an amended agreement or changes to other identifying information about the issuer and its submitted agreements to the CFPB, or May 1 of each year (for updates between the last submission and April 1 of that year). Short form and long form disclosures may be provided to the CFPB as separate addenda to the agreement, rather than integrated into the agreement or as a single addendum.

Regulation Z

The CFPB's rules cover overdraft credit features offered in connection with prepaid accounts where the credit features are offered by the prepaid account issuer, its affiliates, or its business partners with certain exceptions. The CFPB is expanding the exception in 12 CFR 1026.61(a)(4) that allows prepaid account issuers to provide certain incidental forms of credit structured as a negative balance on the asset feature of prepaid accounts without triggering Regulation Z and the other protections for hybrid prepaid-credit cards. Previously, the exception only applied where (1) the prepaid card could not access credit from a covered separate credit feature accessible by a hybrid prepaid-credit card; (2) the prepaid account issuer had a general policy and practice of declining transactions that will take the account negative; and (3) the prepaid account issuer customarily did not charge credit-related fees. Section 1026.61(a)(4), as amended, permits a prepaid account issuer to take advantage of the exception with respect to the negative balance even if a covered separate credit feature offered by a business partner is attached to the prepaid account, so long as the other requirements are met.

Creditors offering these covered overdraft credit features in connection with a prepaid account are required to inform consumers of the costs and terms before consumers use the credit feature and inform consumers of certain subsequent changes to the terms of the credit feature. The initial required information includes the finance charge and other charges, the Annual Percentage Rate (APR), a description of how balances subject to a finance charge are calculated, and any collateral used to secure repayment. If the creditor changes certain terms initially disclosed, or increases the minimum periodic payment, a written change-in-terms notice generally must be provided to the consumer at least 45 days prior to the effective date of the change.

Creditors are required to provide a written periodic statement of activity for each billing cycle. The statement must be provided for each account that has a balance of more than $1 or on which a finance charge is imposed, and the statement must include a description of activity on the account, the opening and closing balances, any finance charges imposed, and payment information.

Creditors are required to notify consumers about their rights and responsibilities regarding billing errors and must provide either a complete statement of billing rights annually or a summary of those billing rights and responsibilities on each periodic statement. If a consumer alleges a billing error, the creditor must provide, within 30 days of receipt, an acknowledgment that the creditor received the consumer's error notice. The creditor must report on the results of its investigation within 90 days. If a billing error did not occur, the creditor must provide an explanation as to why the creditor believed an error did not occur and provide documentary evidence to the consumer upon request. The creditor must also notify the consumer of the portion of the disputed amount and related finance or other charges that the consumer still owed and when payment of those amounts was due.

Persons offering these covered overdraft credit features in connection with a prepaid account are required when advertising their products to include certain basic credit information if the advertisement refers to specified credit terms or costs. Persons offering these features in connection with a prepaid account are required to send copies of the overdraft credit feature agreement to the CFPB. Lastly, persons offering these features in connection with a prepaid account must provide additional disclosures with solicitations and applications. Such card issuers must disclose key terms of the account, such as the APR, information about variable rates, and fees such as annual fees, minimum finance charges, and transaction fees for purchases.

Affected Public: Businesses or other for-profit entities.

Burden Estimates:

Regulation E:

Estimated Number of Respondents: 1,106.

Estimated Annual Burden: 6,605 hours.

Regulation Z: The CFPB has indicated that the only respondents affected by these changes are those that they regulate. Therefore, the OCC will not be taking any burden for these changes.

Frequency of Response: On occasion.

Comments: On May 20, 2019, the OCC issued a notice for 60 days of comment concerning the collection, 84 FR 22931. No comments were received. Comments continue to be invited on:

(a) Whether the collections of information are necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimates of the information collection burden;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation,

maintenance, and purchase of services to provide information.

Dated: October 25, 2019.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2019–23960 Filed 11–1–19; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning treatment of shareholders of certain passive foreign investment companies.

DATES: Written comments should be received on or before January 3, 2020 to be assured of consideration.

ADDRESSES: Direct all written comments to Dr. Philippe Thomas, Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Kerry Dennis, at (202) 317–5751 or Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington DC 20224, or through the internet, at *Kerry.Dennis@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Treatment of Shareholders of Certain Passive Foreign Investment Companies.

OMB Number: 1545–1507.

Regulation Numbers: TD 8701, TD 8178, and TD 9231.

Abstract: The reporting requirements affect United States persons that are direct and indirect shareholders of passive foreign investment companies (PFICSs). The requirements enable the Internal Revenue Service to identify PFICs, United States shareholders, and transactions subject to PFIC taxation and verify income inclusions, excess distributions, and deferred tax amounts.

Current Actions: There are no changes being made to the regulations at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals, business or other for-profit organizations, and not-for-profit institutions.

Estimated Number of Respondents: 406,250.

Estimated Time per Respondent: 31 minutes.

Estimated Total Annual Burden Hours: 212,500 hours.

The following paragraph applies to all of the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 29, 2019.

Philippe Thomas,

Supervisor Tax Analyst.

[FR Doc. 2019–24011 Filed 11–1–19; 8:45 am]

BILLING CODE 4830–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1, 11, 16, et al.
Laboratory Accreditation for Analyses of Foods; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 11, 16, and 129

[Docket No. FDA–2019–N–3325]

RIN 0910–AH31

Laboratory Accreditation for Analyses of Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is proposing to amend its regulations to establish a program for the testing of food in certain circumstances by accredited laboratories, as required under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Establishing such a program will help FDA improve the safety of the U.S. food supply and protect U.S. consumers by helping ensure that certain food testing of importance to public health is conducted subject to appropriate oversight and in accordance with appropriate model standards, and produces reliable and valid test results.

DATES: Submit either electronic or written comments on the proposed rule by March 3, 2020. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by March 3, 2020 (see the ''Paperwork Reduction Act of 1995'' section of this document).

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 3, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 3, 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–3325 for Laboratory Accreditation for Analyses of Foods. 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 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: *http://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 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, ''Laboratory Accreditation for Analyses of Foods.''

FOR FURTHER INFORMATION CONTACT: Timothy McGrath, Staff Director, Food and Feed Laboratory Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rm. 3142, Rockville, MD 20857, 301–796–6591, email: *timothy.mcgrath@fda.hhs.gov.*

With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown Street, North Bethesda, MD 20852, 301–796–5733, email: *PRAStaff@fda.hhs.gov.*

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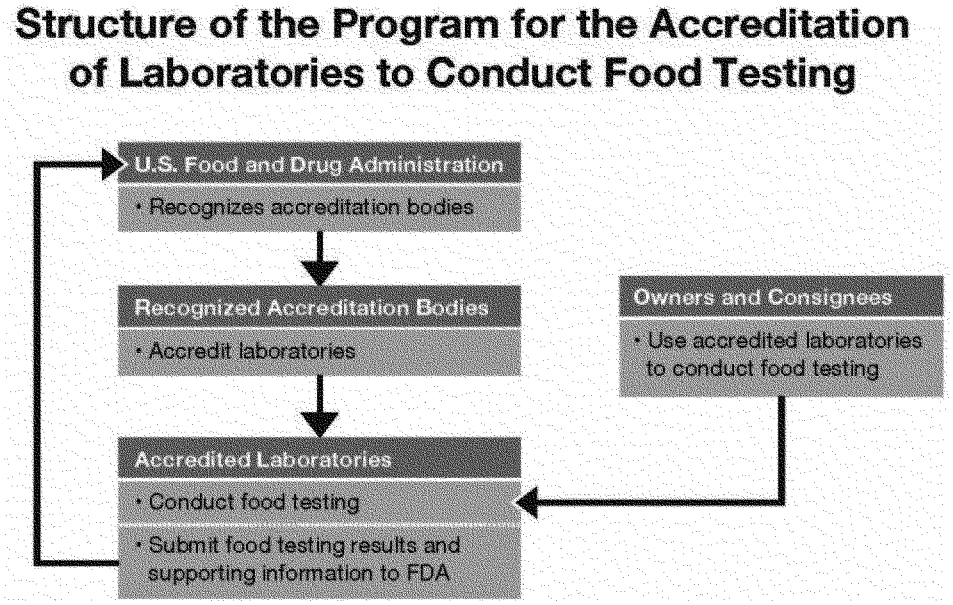
I. Executive Summary

A. Purpose and Coverage of the Proposed Rule

This proposed rule, if finalized, would establish a new program for food testing by accredited laboratories. The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), section 202(a), added section 422 to the FD&C Act (21 U.S.C. 350k), which requires us to establish this program.

You would be subject to this rule, if finalized, if you are a recognized accreditation body, an entity seeking to be a recognized accreditation body, an accredited laboratory, or an entity seeking to be an accredited laboratory, for purposes of food testing as specified in this proposed rule. You would also be subject to this rule if you are an owner or consignee required to use an accredited laboratory to conduct food testing as specified in this proposed rule. Although participation in this program is voluntary for laboratories, laboratories would only be able to conduct testing described in proposed § 1.1107 if they are accredited under this proposed program.

Under this proposed rule FDA would recognize accreditation bodies that would accredit laboratories to conduct food testing. The program structure is portrayed in the following diagram:



This proposed program for the testing of food by accredited laboratories would establish the oversight, uniformity, and standards necessary to help ensure that the results of certain food testing of importance to public health are reliable and accurate, and, in turn, establishment of the program would substantially improve our capability to protect U.S. consumers from unsafe food.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule contains model standards that laboratories must meet in order to be and stay accredited. The proposed rule, if finalized, would establish a publicly available list of accreditation bodies and laboratories that have been recognized or accredited under this program. Results of food testing conducted by laboratories under the program would be required to be sent directly to FDA. Laboratories accredited under this program would be required to submit to FDA some analytical reports, but for certain laboratories less documentation would

be required than we currently expect as part of a private laboratory analytic package.

This proposal contains eligibility requirements for accreditation bodies to qualify for recognition and requirements that accreditation bodies must meet once recognized, such as requirements related competency and conflict of interest safeguards. The proposed rule also contains eligibility requirements for laboratories to qualify for accreditation by a recognized accreditation body and requirements that laboratories must meet once accredited, such as requirements related to conflicts of interest, analysis, and records. These requirements will help ensure the effectiveness of the recognized accreditation bodies and accredited laboratories under this program. This proposal also contains procedures we would follow to recognize accreditation bodies under this program and procedures for accreditation bodies to follow to accredit laboratories under this program. This proposed rule also contains regulatory procedures and requirements relating to our monitoring and oversight of recognized accreditation bodies and accredited laboratories.

This proposed rule would apply when food testing is conducted in certain circumstances. ''Food testing'' and ''testing of food'' would include the analysis of human or animal food. ''Food testing'' and ''testing of food'' would also include testing of the food growing or manufacturing environment (*i.e.,* ''environmental testing'').

We seek comments on all aspects of this proposed rule.

C. Legal Authority

Section 422(a)(1)(A) the FD&C Act, which was added by section 202(a) of FSMA, directs us to establish a program for the testing of food by accredited laboratories. Therefore, section 422 of the FD&C Act provides FDA with authority for these proposed requirements, which outline what would be required of participants in the program for the testing of food by accredited laboratories. FDA also derives authority for these proposed requirements from section 701(a) of the FD&C Act (21 U.S.C. 371(a)), which authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act.

D. Costs and Benefits

The costs of the proposed rule, if finalized, would be incurred primarily by participating accreditation bodies, participating labs, shell-egg producers, sprouts producers, bottled water manufacturers, and owners and consignees of human and animal food offered for import covered by the proposed rule. We would incur costs to establish and maintain the program for recognizing accreditation bodies hoping to participate in our program, assessing participating accreditation bodies and participating labs, and for reviewing associated documents and reports. The present value of the cost of the proposed rule, if finalized, would range from $34 million to $78 million when discounted by 7 percent over 10 years. When discounted by 3 percent over 10 years the present value of the cost would range from $39 million to $92 million.

The proposed rule, if finalized, would generate some quantified and unquantified benefits. Quantified benefits include cost-savings from the proposed clarifications of the process for compiling, submitting and reviewing analytical reports for human and animal food offered for import covered under the proposed rule, and a reduced burden from the proposed abbreviated reporting requirements. In addition, there would be savings from fewer false positive test results. We anticipate a reduction in the number of foodborne illnesses from fewer false negative test results for human and animal food offered for import covered under the proposed rule and for shell eggs, sprouts, bottled water, and other food subject to specific testing requirements covered under the proposed rule. Unquantified benefits could include fewer illnesses from deterring unsafe manufacturing practices by all entities affected by the proposed rule. The present value of the quantified benefits of the proposed rule, if finalized, would range from $26 million to $81 million when discounted by 7 percent over 10 years. When discounted by 3 percent over 10 years the present value of the quantified benefits would range from $32 million to $98 million.

II. Table of Abbreviations and Acronyms Commonly Used in This Document

Abbreviation/ acronym	What it means
ANSI	American National Standards Institute.
BAM	Bacteriological Analytical Manual.
CFR	Code of Federal Regulations.
CPSC	Consumer Product Safety Commission.
DWPE	Detention Without Physical Examination.
EO	Executive Order.
E. coli	*Escherichia coli.*
FDA	United States Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FR	Federal Register.
FSMA	FDA Food Safety Modernization Act.
FSVP	Foreign Supplier Verification Programs.
GAO	Government Accountability Office.
HHS	Health and Human Services.
IBR	Incorporation by Reference.
IEC	International Electrotechnical Commission.
ILAC	International Laboratory Accreditation Cooperation.
ISO	International Organization for Standardization.
MRA	Mutual Recognition Arrangement.
NIST	National Institute of Standards and Technology.
NTTAA	National Technology Transfer and Advancement Act of 1995.
OMB	Office of Management and Budget.
ORA	Office of Regulatory Affairs.
PLAP	Private Laboratory Analytical Package.
PRA	Paperwork Reduction Act.
PRIA	Preliminary Regulatory Impact Analysis.
IEC	International Electrotechnical Commission.
U.S.C	United States Code.
WTO	World Trade Organization.

III. Background

A. FDA Food Safety Modernization Act

On January 4, 2011, President Obama signed FSMA into law. FSMA is intended to allow FDA to better protect public health by helping ensure the safety and security of the U.S. food supply and enables us to focus more on preventing food safety problems rather than primarily reacting to them once they surface. FSMA also provides us with new enforcement authorities designed to achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, FSMA gives us important new tools to better ensure the safety of imported foods and encourages partnerships with State, local, tribal, and territorial authorities. In implementing FSMA, we prioritized the development of seven foundational rules that provide the framework for risk-based preventive controls and enhance our ability to oversee their implementation by industry for both domestic and imported food. We have finalized these foundational rules and begun their implementation while also developing additional programs required by FSMA, including a program for food testing by accredited laboratories, as proposed in this document.

B. Food Testing Under FSMA

FSMA recognized that food testing could perform different roles in supporting a modern food safety system. For example, section 418(f)(4) of the

FD&C Act (21 U.S.C. 350g) provides for the use of environmental and product testing programs as part of required verification that preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards (food testing under such requirements may be conducted for biological, chemical, physical, radiological hazards, or, most commonly, microbiological hazards). Section 805(c)(4) of the FD&C Act (21 U.S.C. 384a) states that verification activities under a foreign supplier verification program may include periodically testing and sampling shipments. Under these provisions, food testing is used to verify that control measures, including those related to suppliers, are controlling the identified hazards. In implementing these provisions in the regulations for preventive controls for human food and foreign supplier verification programs, we attempted to provide flexibility by specifying that they apply as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system. 21 CFR 117.165(a); accord 21 CFR 507.49(a) (parallel provision in the regulation for preventive controls for animal food); 21 CFR 1.506(d)(1)(ii)(B) (including sampling and testing of a food among other appropriate supplier verification activities).

FSMA, in establishing section 422 of the FD&C Act, also underscores that food testing can play a role in detecting and responding to food safety problems. Section 422(b)(1) of the FD&C Act requires that food be tested by accredited laboratories in four circumstances:

- In response to a specific testing requirement under the FD&C Act or implementing regulations, when applied to address an identified or suspected food safety problem;
- As required by the Secretary of Health and Human Services (HHS), as the Secretary deems appropriate, to address an identified or suspected food safety problem;
- In support of admission of an article of food under section 801(a) of the FD&C Act (21 U.S.C. 381(a)); and
- Under an import alert through successful consecutive tests.

With one exception, section 422(b)(2) of the FD&C Act requires the results of food testing conducted under section 422(b)(1) to be sent directly to FDA, thereby allowing FDA to review the test results.

In food manufacturing or processing facilities, followup or corrective action testing is often conducted as part of corrective actions when an environmental pathogen or indicator organism (*i.e.,* an organism that indicates conditions in which an environmental pathogen may be present) is found during environmental monitoring. See current good manufacturing practice and hazard analysis and risk-based preventive controls for human food proposed rule, 78 FR 3646 at 3816, January 16, 2013. Corrective action testing may also occur in response to the results of product testing, although testing cannot ensure the absence of a hazard. Id. at 3819. The accredited laboratory testing requirement in this proposed rule would not apply to all corrective action testing, but would apply to food testing conducted under specific testing requirements in the FD&C Act and implementing regulations that ''address an identified or suspected food safety problem'', and in food testing orders that we would issue ''to address an identified or suspected food safety problem.'' As discussed in section VI.B.1, we have tentatively determined that an ''identified food safety problem'' could be present where a specific article of food violates a provision of the FD&C Act that relates to food safety and a ''suspected food safety problem'' could be present where there is reasonable suspicion that a specific article of food violates a provision of the FD&C Act that relates to food safety or where there is particularized suspicion of a food safety problem that does not necessarily render food violative. An example of a specific testing requirement in our FD&C Act regulations that would ''address an identified or suspected food safety problem'' and be subject to section 422(b)(1)(A)(i) of the FD&C Act is a requirement for bottled water producers to test, after corrective measures have been applied, 5 samples collected over a 24-hour period from the same site that previously tested positive for *Escherichia coli (E.coli).* See § 129.35(a)(3)(i) (21 CFR 129.35(a)(3)(i)). In this example, the presence of *E. coli* in the tested source water would constitute an ''identified or suspected food safety problem'' because its presence in the source water is not considered water of a safe quality as is required for bottled drinking water by § 129.35(a)(1).

C. Import-Related Food Testing and Detention Without Physical Examination (DWPE) Procedure

Section 422(b)(1)(B) of the FD&C Act requires accredited laboratory food testing where testing of food is conducted as part of testimony for the purposes of section 801(a) of the FD&C Act. Under section 801(a)(3) of the FD&C Act, we may refuse admission of an imported food into the United States if the food is, or appears to be, adulterated or misbranded. Pending our decision to refuse admission, section 801(a) of the FD&C Act allows the owner or consignee of the imported article of food to introduce evidence regarding the admissibility of the food. See also 21 CFR 1.94(a). Owners and consignees often hire private laboratories to test the food product and submit the results of the testing, along with associated analysis and data, to us to show that the imported food complies with the FD&C Act. If we determine that the food testing results are valid and that they demonstrate the detained food product does not violate the FD&C Act, we will release the food from detention and allow it to proceed into the United States.

The DWPE procedure allows us to detain a product without physically examining it at the time of entry. We use the DWPE procedure when there exists a history of the importation of violative products, or products that may appear violative, or when other information indicates that future entries may appear violative. Import alerts inform FDA field staff and the public that we have enough evidence to allow for DWPE of products that appear to be in violation of FDA laws and regulations. Depending on the reason for DWPE, owners and consignees may hire private laboratories to test a food product in an attempt to overcome the appearance of the violation and release the food from detention.[1]

D. Testing of Imported Food by Private Laboratories

As the volume of food offered for import to the United States increased in recent decades, our use of the DWPE procedure also increased, as did concomitant food testing by private laboratories on behalf of importers. From January 1, 2016, through December 31, 2017, we received food testing submissions, known as private laboratory analytical packages (PLAPs),

[1] In both the domestic and import arenas, the owner or consignee of a food may accept that a food product is violative and offer to recondition the food to make it nonviolative (*e.g.,* by subjecting an adulterated food to a treatment that cures the adulteration), divert human food for use as animal food, and/or recondition the food to make the food not subject to our enforcement authorities (*e.g.,* by processing the food in a manner that makes it into a type of product we do not regulate). After food has been reconditioned and/or identified for diversion to animal food, the owner or consignee of the food (who we also refer to herein as the ''importer'' in the import context) may have food testing conducted on the product to demonstrate to us that the product is safe for the intended use.

from approximately 100 different private laboratories. See FDA Memorandum, ''Assessment of DWPE Sampling and Analysis Data to Determine What Portion of Sampling and Analysis of Food under DWPE is Conducted by Accredited Entities'' (Ref. 1). Historically, we relied on Agency procedural documents and communications from FDA offices that review PLAPs to encourage private laboratories to meet certain standards for testing and sampling. We previously have observed that our recommended procedures for private laboratories were ''not sufficiently specific,'' which may have contributed to a lack of consistency in standards for testing and sampling across FDA districts (requirements pertaining to sampling services and private laboratories used in connection with imported food proposed rule, 69 FR 23460 at 23468, April 29, 2004). In addition, the lack of regulatory requirements for PLAP content has sometimes complicated our scientific review of PLAP submissions from private laboratories.

Concerns also have periodically arisen regarding importers' manipulation or substitution of the samples a private laboratory tests, and practices such as ''testing into compliance,'' in which multiple samples from a shipment are tested, but only those results that would allow the shipment to enter the United States are submitted to us. See, *e.g.,* ''The Safety of Food Imports: Fraud & Deception in the Food Import Process; Hearings Before the Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations,'' September 10, 1998 (statement of ''Former Customs Broker'') (Ref. 2, pages 26–35 and 137–140).

In attempts to address these issues, FDA and others have taken several actions to improve coordination between FDA and private laboratories and improve the safety of food imports. This section describes several of these activities up to and including the enactment of FSMA section 202(a).

In 1996 we held several public meetings across the country to discuss how FDA might improve its policies and procedures relating to the use of private laboratories to test food offered for import. (61 FR 29416, June 10, 1996). These public meetings resulted in an action plan which suggested, among other things, that we establish consistent and objective standards for the format and content of food testing results and analytical information that private laboratories submit to us, that we require independent sampling of such food prior to the food's analysis by a private laboratory, and that we require the laboratory to send the results of all such food testing directly to us (see discussion of the plan in the 2004 proposed rule, 69 FR 23460, at 23460, April 29, 2004).

In 2003, we added a section on ''Private Laboratory Guidance'' to FDA's Office of Regulatory Affairs (ORA) Laboratory Manual (ORA Laboratory Manual) (Ref. 3). This document updated procedures for reviewing PLAPs (which contain sampling collection reports, testing results, and associated analytical information) submitted to us as testimony relevant to the admissibility, destruction, or reconditioning of FDA-regulated articles offered for import.

Recognizing a need for oversight over sampling services and private laboratories testing of imported food on behalf of importers, in the **Federal Register** of April 29, 2004, we proposed a rule on ''Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food'' (the 2004 proposed rule). We designed the 2004 proposed rule with the goals of deterring the importation of unsafe food, establishing uniformity in the practices of samplers and laboratories testing imported food for FDA regulatory purposes, and improving the reliability and scientific validity of the food testing analytical information that FDA uses to make food import admissibility decisions. The proposed rule would have required, among other requirements, that samples of food to be tested be properly identified, collected, and maintained; that laboratories conducting food testing use validated or recognized analytical methods; and that laboratories conducting food testing submit the analytical results of the food testing directly to FDA. Id.

The 2004 proposed rule would not have required laboratories conducting food testing to be accredited because we determined that doing so would have been premature. Id. at 23464. We did, however, in the preamble to the 2004 proposed rule strongly encourage laboratories conducting such food testing to become accredited. Id. Most comments on the accreditation issue contended that accreditation to International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025:2005, ''General Requirements for the Competence of Testing and Calibration Laboratories'' (Ref. 4), would substantially enhance the effectiveness of the rule. We withdrew the 2004 proposed rule on August 5, 2005 (see 70 FR 64553 at 64590, October 31, 2005).[2]

In November 2007, an Interagency Working Group on Import Safety, made up of representatives from 12 federal departments and agencies, presented an Action Plan for Import Safety to President Bush containing recommendations and action steps to further improve the safety of imports entering the United States (Ref. 5). One of these action steps was that we issue guidance setting ''standards for the sampling and testing of imported products, including the use of accredited laboratories submitting data to FDA to assist in evaluating whether an appearance of a violation may be resolved.''

On January 29, 2008, the Government Accountability Office (GAO) recommended, in testimony to the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, that we consider accrediting private laboratories to test seafood. See GAO, ''Federal Oversight of Food Safety: FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out Is Critical,'' GAO–08–435T (Ref. 6), at page 7). This recommendation, which GAO had originally made in 2004, was intended to help us leverage outside resources and provide greater assurance about the quality of the laboratories importers use for seafood products subject to DWPE. See GAO, ''Food Safety: FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements are Needed,'' GAO–04–246 (Ref. 7), at page 6.

On January 16, 2009, under the Action Plan for Import Safety, we issued a draft guidance document entitled ''Guidance for Industry: Submission of Laboratory Packages by Accredited Laboratories'' (the 2009 draft guidance) (Ref. 8), in which we recommended a voluntary accreditation program for laboratories conducting testing to support the admissibility of articles offered for import of all product types that FDA regulates. (See 74 FR 3056, January 16, 2009).

We acknowledged in the 2009 draft guidance that the landscape of laboratory accreditation had changed since we published the 2004 proposed rule, including a general trend toward laboratory accreditation and wider industry adoption of the ISO/IEC 17025 standard, as well as accreditation of FDA's own laboratories to the ISO/IEC 17025 standard. The 2009 draft guidance also noted that rigorous

[2] See *https://www.govinfo.gov/content/pkg/GPO-UA-2005-10-31/pdf/GPO-UA-2005-10-31-8.pdf.*

accreditation standards provide FDA and industry with greater confidence that laboratories receiving accreditation have sufficient technical capability, trained personnel, and quality management systems to perform the specific testing methods for which they are accredited. We further noted in the 2009 draft guidance that laboratory accreditation bodies' continuing oversight over accredited laboratories would enhance the Agency's confidence in the accredited laboratories' analyses and results. To encourage laboratories to voluntarily seek accreditation, the 2009 draft guidance recommended that laboratories that became accredited would be permitted to submit ''abbreviated'' laboratory packages to FDA in lieu of full PLAPs. Under the 2009 draft guidance, abbreviated laboratory packages consisted of documents identifying the entry from the importer of record, a summary of analysis, and affirmation from the laboratory director regarding the accuracy of the sampling and analysis. Full PLAPs, in turn, include the details of the analyses performed, including underlying raw data and supporting materials such as sample collection reports, validation and verification studies, analyst training records, etc.

The 2009 draft guidance further recommended that accreditation bodies that accredit laboratories conducting import admissibility testing on FDA-regulated products should operate in accordance with ISO/IEC 17011:2004 ''General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies'', as this would help ensure the competency of the accreditation bodies. The 2009 draft guidance additionally recommended that accreditation bodies should be signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), by which they would agree to maintain conformity with the current version of ISO/IEC 17011 and ensure that all laboratories they accredit comply with appropriate laboratory standards. The 2009 draft guidance also recommended that accreditation bodies accredit laboratories for specific testing methodologies used to generate test results submitted to FDA, and that they do so by assessing laboratories' conformance to ISO/IEC 17025:2005.[3] The 2009 draft guidance noted ''widespread agreement,'' including by our own laboratories, that ISO/IEC 17025 was the most internationally recognized and accepted standard for testing laboratories.

On the issue of sampling, the 2009 draft guidance recommended that accreditation bodies review laboratories' sampling procedures to ensure the integrity, accuracy, and representative quality of samples, including samples collected by laboratories themselves and samples collected by sampling services under contract to the laboratory. The 2009 draft guidance further recommended that importers provide us with advance notice that they intend to use a particular accredited laboratory and that an abridged laboratory package would be submitted under the guidance, and that accredited laboratories conducting the analysis directly submit to us the results of all testing on the articles at issue.

Almost all comments we received in response to the 2009 draft guidance supported our recommendation for laboratory accreditation. The 2009 draft guidance was never finalized and was withdrawn in May 2015 (see 80 FR 26059, May 6, 2015). However, we considered both the 2004 proposed rule and the 2009 draft guidance and the comments we received in response to both documents, in developing this proposal.

E. Current Industry Practices Relating to Accreditation Bodies, Accreditation of Laboratories, and Food Testing

FDA has not had a policy of weighing food testing results differently depending on whether the laboratory that conducted the food testing is accredited, and therefore we generally do not track the accreditation status of private laboratories that conduct food testing in either the domestic or import arenas. However, we are able to make some reasonable inferences and conclusions regarding the laboratories that have conducted testing related to imports, with the data we do have.

With regards to the testing of imported foods, our analysis of the data in our internal systems (Ref. 1) indicates that just over one hundred different private laboratories submitted (although in some cases the laboratory would submit the results and supporting information to the importer, who would then submit them to us) analyses and results to us between January 1, 2016, and December 31, 2017, of food offered for import that we had detained. Ten of those laboratories submitted approximately 84 percent of the analyses. By examining publicly available records from accreditation bodies regarding the accreditation status of those laboratories, we concluded that all 10 of those laboratories are accredited to ISO/IEC 17025. This indicates that the large majority of import-related food testing results that we receive come from laboratories that are accredited to ISO/IEC 17025. We found no laboratories conducting analyses in support of food offered for import that we had detained that were accredited to any standard other than ISO/IEC 17025. We also found that all of the accredited laboratories that submitted import-related food testing results were accredited by accreditation bodies that are full members of ILAC and signatories to the ILAC MRA, which requires signatories to have been peer evaluated in accordance with ISO/IEC 17011 to demonstrate competence. ILAC MRA signatories must maintain conformance with ISO/IEC 17011 (see, *e.g.,* IAF/ILAC ''Multi-Lateral Mutual Recognition Arrangements (Arrangements): Requirements and Procedures for Evaluation of a Single Accreditation Body'' (Ref. 10, p. 8)).

F. U.S. Government Policies on Consensus Standards

Implementation of section 422 of the FD&C Act occurs against the backdrop of broader U.S. federal policies on consensus standards under the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Pub. L. 104–113).

The NTTAA, together with the Office of Management and Budget (OMB) Circular A–119, ''Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities'' (most recently revised on January 27, 2016) (Ref. 11), directs federal agencies to use voluntary consensus standards in their procurement and regulatory activities in lieu of government-unique standards, except where inconsistent with law or otherwise impractical. OMB Circular A–119 states that the use of voluntary consensus standards, whenever practicable and appropriate, is intended to: (1) Eliminate the cost to government of developing its own standards and decrease the cost of goods procured and the burden of complying with Agency regulation, (2) provide incentives and opportunities to establish standards that serve national needs, encouraging long-term growth for U.S. enterprises and promoting efficiency, economic competition, and trade, and (3) further the reliance upon private sector expertise to supply the

[3] FDA also recommended that laboratories incorporate in their implementation of ISO/IEC 17025 the factors established in the AOAC International's ''Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals, and Aid to Interpretation of ISO/IEC 17025:2005'' (Ref. 9).

Federal government with cost-efficient goods and services.

Additionally, as directed by OMB in Circular A–119 (Ref. 11), the National Institute of Standards and Technology issued policy guidance on Federal conformity assessment activities [4] (Federal conformity assessment guidance), published in the **Federal Register** of August 10, 2000 (65 FR 48894), and codified at 15 CFR part 287. The guidance recommends that, as appropriate, Federal Agencies use relevant guides or standards for conformity assessment practices from domestic and international standardizing bodies (*e.g.,* the ISO, the IEC, and the Codex Alimentarius Commission).[5] The guidance also notes that each agency retains the responsibility, and authority, to select the conformity assessment activities and procedures (*i.e.,* guides and standards) that will best meet its legislative mandates and programmatic objectives.

Further, section 422(a)(6) of the FD&C Act requires us to ''consult existing standards for guidance'' in the course of developing model standards that a laboratory must meet to be accredited by a recognized accreditation body for a specified sampling or analytical testing methodology.

In developing this proposed rule, two relevant voluntary consensus standards stood out as containing globally-recognized and widely-used requirements relevant to the program for food testing by accredited laboratories: ISO/IEC 17011:2017, ''Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies'' (ISO/IEC 17011:2017) (Ref. 12), for accreditation bodies that would be recognized under the program, and ISO/IEC 17025:2017, ''General Requirements for the Competence of Testing and Calibration Laboratories'' (ISO/IEC 17025:2017) (Ref. 13), for laboratories that would be accredited under the program.

Although we are proposing to require accreditation bodies to meet ISO/IEC 17011:2017 entirely, we are proposing to not require accredited laboratories to meet certain aspects of ISO/IEC 17025:2017 that would be inconsistent with section 422 of the FD&C Act or would be impractical for use in our program. We are also proposing to require accredited laboratories to meet certain requirements in addition to ISO/IEC 17025:2017. For further discussion on this issue, please see sections VI.C and VI.D (regarding the proposed requirements under this program for accreditation bodies) and sections VI.F and VI.G (regarding the proposed requirements under this program for laboratories). For information on accessing these consensus standards, please see section III.G.

We invite public comment on whether the voluntary consensus standards we cite are the appropriate standards upon which to base this rulemaking.

G. Incorporation by Reference

We are proposing to incorporate the following consensus standards by reference, with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 553(a) and 1 CFR part 51:

- ISO/IEC 17011:2017, ''Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies,'' Second edition, November 2017 (Ref. 12), and
- ISO/IEC 17025:2017, ''General Requirements for the Competence of Testing and Calibration Laboratories,'' Third edition, November 2017 (Ref. 13).

For an overview of ISO/IEC 17011:2017, please see section VI.C. of the preamble. For an overview of ISO/IEC 17025:2017, please see section VI.F of the preamble.

The consensus standards proposed to be incorporated by reference are available to the public in four different ways: (1) Generally, the most convenient way for interested parties to view these consensus standards is via the special link created by the American National Standards Institute (ANSI), which is a private non-profit organization that supports the U.S. voluntary standards and conformity assessment system. ISO/IEC 17011:2017 and ISO/IEC 17025:2017 are available to view through the following link free of charge: *https://www.surveymonkey.com/r/KFJMZ67*. Please note that you must have certain software on your computer (available free of charge through following the process on this website) and complete a registration form (when prompted by the process on this website) to view these consensus standards via the website facilitated by ANSI. Alternatively, interested parties may: (2) Examine these standards at Dockets Management Staff at FDA at the locations listed in proposed §§ 1.1113(b) and 1.1138(a)(2), (3) purchase copies of these standards from ISO or from IEC, or (4) purchase copies of these standards from any other source from which the user is assured that the copy to be received is an accurate and current version of the standard.

IV. FSMA Public Meetings, Comments Related to Other FSMA Rulemakings, and Stakeholder Input

Since the enactment of FSMA, we have reached out to stakeholders in the food industry, the international community, standards organizations, accreditation and certification bodies, consumer groups, government agencies, and other interested parties to gain input and perspective on how to best implement FSMA. Such interested parties have also provided comments to us at their own initiative and requested meetings with us at their own initiative to discuss our implementation of FSMA. The input and perspectives we gained through these comments and meetings helped shape this proposed rule.

Since the enactment of FSMA, we have also received several comments from interested parties specifically regarding our implementation of section 422 of the FD&C Act. We received many such comments in response to our solicitation of comments regarding our implementation of other aspects of FSMA, for example, with regards to the accreditation of third-party auditors (see section 808 of the FD&C Act, added by FSMA section 307), hazard analysis and risk-based preventative controls (see section 418 of the FD&C Act, added by FSMA section 103), and standards for produce safety (see section 805 of the FD&C Act, added by FSMA section 105). The most common issue discussed in those comments related to what scenarios should require food testing to be conducted by accredited laboratories under section 422(b)(1) of the FD&C Act. Other issues discussed in such comments include the circumstances under which we should allow variance from the requirement to submit to FDA the results of all tests conducted under this proposed program. There were also a small number of comments regarding the implementation of section 422 of the FD&C Act submitted to the docket established to help FDA identify existing ways of achieving meaningful burden reduction while still allowing us to achieve our public health mission and fulfill our statutory obligations. To the extent practicable, we tried to consider all comments in drafting this

[4] The Federal conformity assessment guidance defines conformity assessment activities, in part, as ''any activity concerned with determining directly or indirectly that requirements are fulfilled'' (see 15 CFR 287.2).

[5] The Codex Alimentarius Commission, established by Food and Agriculture Organization of the United Nations and the World Health Organization (WHO) in 1963 develops harmonized international food standards, guidelines, and codes of practice to protect the health of the consumers and ensure fair trade practices in the food trade. The Commission also promotes coordination of all food standards work undertaken by international governmental and non-governmental organizations.

proposed rule. However, to ensure that we consider your comment in the context of this rulemaking, you should resubmit in response to this proposed rule any comment(s) you previously submitted regarding our implementation of section 422 of the FD&C Act.

Since the enactment of FSMA, we have also met with several stakeholders, some of who requested meetings with FDA to discuss their current programs and to share their views and recommendations for our implementation of section 422 of the FD&C Act, and others whom we contacted in order to learn from their relevant experience and subject matter expertise. Topics for our meetings with these stakeholders included the general structure and function of the program, the standards to which accreditation bodies, sampling services, and laboratories should adhere in order to be recognized or accredited under this proposed program, and how sampling services should be addressed in the program. We discuss issues relevant to this rulemaking that were covered during these meetings in Section VI, Description of the Proposed Rule of this NPRM.

In this proposed rule we have intended to draft a practical, flexible, and effective approach to the program for the testing of foods by accredited laboratories. We seek comments on all aspects of this proposal, including comments about any potential impacts of this proposed rule.

V. Legal Authority

We are issuing this proposed rule under the FD&C Act and FSMA. As noted, section 202(a) of FSMA, ''Laboratory Accreditation for Analyses of Foods'', amends the FD&C Act to create a new provision, section 422, under the same name. Section 422 of the FD&C Act directs us to establish a program for the testing of food by accredited laboratories and provides several requirements for the program.

Additionally, section 701(a) of the FD&C Act gives FDA the authority to publish regulations for the efficient enforcement of the FD&C Act. The requirements discussed in this proposed rule would allow FDA to efficiently enforce section 422 of the FD&C Act. Thus, our legal authority for this proposed rule is derived primarily from section 422 and section 701(a) of the FD&C Act. Further, we also note that this rule is consistent with section 404 of FSMA (21 U.S.C. 2252), which states that nothing in FSMA should be construed in a manner that is inconsistent with the agreement establishing the World Trade Organization (WTO) or any other treaty or international agreement to which the United States is a party.

VI. Description of the Proposed Rule

In section 422 of the FD&C Act Congress directs us to establish a program for the testing of food by accredited laboratories. We are proposing to add new subpart R, ''Accreditation of Laboratories to Conduct Food Testing,'' to part 1 (21 CFR part 1) (''General Enforcement Regulations'') and amend our regulations in parts 11 (''Electronic Records; Electronic Signatures''), and 16 (''Regulatory Hearing before the Food and Drug Administration'') (21 CFR parts 11 and 16) to establish and implement a program for food testing by accredited laboratories, as required by section 422 of the FD&C Act. We are also proposing to amend part 129 (21 CFR part 129) (''Processing and Bottling of Bottled Drinking Water'') to ensure that the requirements in part 129 are consistent with the requirements of section 422 of the FD&C Act. We are also proposing to revise certain testing provisions in part 1, Subpart M (''Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications''), in the interest of consistency with this proposed rule and in response to additional information we have gathered, in developing this proposed rule, about the number and capacity of laboratories accredited under ISO/IEC 17025 to conduct food testing.

We also note that in November 2017, ISO/IEC released new versions of ISO/IEC 17011 and ISO/IEC 17025. ISO/IEC 17011 and ISO/IEC 17025 were last revised in 2004 and 2005, respectively. The new versions of ISO/IEC 17011 and 17025—ISO/IEC 17011:2017 and 17025:2017—do not represent fundamental changes to the previous versions of ISO/IEC 17011 and ISO/IEC 17025. Rather, the new versions of ISO/IEC 17011 and ISO/IEC 17025 have been technically revised to more accurately reflect current best practices of accreditation bodies and of testing and calibration laboratories.

A. Proposed General Provisions (Proposed §§ 1.1102 Through 1.1103)

1. What definitions apply to this subpart? (Proposed § 1.1102)

We propose to define several terms used in this rule (see proposed § 1.1102). Where possible, we propose to rely on existing statutory and regulatory definitions. Proposed § 1.1102 states that definitions and interpretations contained in section 201 of the FD&C Act (21 U.S.C. 321) will apply to this rule, except as those terms are otherwise defined in this section. We also note here that grammatical variations of the terms defined in proposed § 1.1102 have the same meaning as the defined term, modified as grammatically appropriate. For example, the term to ''accredit,'' although not specifically defined by proposed section § 1.1102, would mean to bestow accreditation, in accordance with how the term ''accreditation'' would be defined by this rule.

Where necessary to provide clarity to this rule, we have developed some additional definitions that align with existing law and regulations, as well as with current practices of the international community, accreditation bodies, food testing laboratories, and the food industry. We seek comments on these proposed definitions, including with respect to whether any of the proposed definitions are unnecessary and with respect to whether any additional terms we use in this proposed rule should be defined.

We propose to define ''accreditation'' to mean a determination by a recognized accreditation body that a laboratory meets the applicable requirements of this program to conduct food testing under this program using one or more methods of analysis. In developing the definition of accreditation, we considered the use of the term accreditation in section 422 of the FD&C Act. Specifically, section 422(a)(6) of the FD&C Act directs us to develop model standards that a laboratory shall meet to be accredited by a recognized accreditation body for a specified sampling or analytical testing methodology and section 422(b)(1) of the FD&C Act provides that food testing under this program may only be conducted by laboratories that have been accredited for the appropriate sampling or analytical testing methodology or methodologies by a recognized accreditation body. These provisions indicate that accreditation under section 422 of the FD&C Act requires a determination by a recognized accreditation body that a laboratory meets our model standards for a specified analytical testing methodology. We also considered the meaning of accreditation in international standards on accreditation, including ISO/IEC 17011:2017 (Ref. 12), which defines accreditation as an attestation ''conveying formal demonstration'' of a conformity assessment body's competence to carry out specific conformity assessment tasks. In the context of the proposed

rule, recognized accreditation bodies would accredit laboratories that they determine meet the applicable requirements of the rule.

The term accreditation as it is used in the proposed rule, refers only to a recognized accreditation body's determination that a laboratory meets the applicable requirements of this program and does not refer to any accreditation outside of this program. For example, although conformance to certain aspects of ISO/IEC 17025:2017 is a prerequisite to becoming accredited by a recognized accreditation body under this proposed rule, the term accreditation, as used in this proposed rule, does not refer to accreditation to ISO/IEC 17025 or to any other standard.

We propose to define ''accredited laboratory'' to mean a laboratory that a recognized accreditation body has determined meets the applicable requirements of this program and has been accredited to conduct food testing using one or more methods of analysis under this program.

We propose to define ''analyst'' to mean an individual who analyzes samples. The term refers to a single individual and does not refer to any other type of entity that is treated as a person for certain legal purposes.

Proposed § 1.1102 would define ''food,'' as having the meaning given in section 201(f) of the FD&C Act, except that it would not include pesticides as defined in 7 U.S.C. 136(u), consistent with the definition of food used in the FSMA Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP) (part 1, Subpart L) and Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications (accredited third-party certification) (part 1, Subpart M) regulations. We have tentatively determined there is no significant reason to define food differently in this proposal. We have not identified a need for food testing under this program to address pesticides as articles of food.

We propose to define ''food testing'' and ''testing of food'' to mean the analysis of food product samples or environmental samples. The terms food testing in sections 422(b)(1) and 422(d) of the FD&C Act, and testing of food in section 422(a)(1)(A) of the FD&C Act, are not defined in the statute. We see two possible ways to interpret and apply these terms. As noted, the FD&C Act has a definition of food at section 201(f), and it therefore may be a reasonable assumption that food testing means only the testing of food as food is defined under section 201(f). Under this approach, food testing would mean only product testing (where product testing includes testing of any food product, including raw materials or other ingredients, in-process foods, or finished products).

The alternative interpretation, which we propose, would interpret food testing to include product testing as well as environmental testing (*e.g.,* testing from the growing, harvesting, manufacturing, processing, packing, or holding environment). We have tentatively concluded that the meaning of food testing, a term that appears only in section 422 of the FD&C Act, is ambiguous and may be interpreted to encompass both product testing and testing that is related to food, that is, environmental testing. Food testing is distinct from ''product testing,'' used in section 418(f)(4) of the FD&C Act, and ''environmental testing programs'' and ''environmental monitoring programs,'' which are used in sections 418(f)(4) and 418(o)(3)(C) of the FD&C Act, respectively. We note that section 202(a) of FSMA is located in title II of FSMA, which is entitled improving capacity to detect and respond to food safety problems, and section 422(b)(1)(A) of the FD&C Act requires accredited laboratory performance of food testing to address an identified or suspected food safety problem. Given the role of environmental testing in determining both the source of contamination and in determining whether such contamination has been eliminated, interpreting food testing to exclude environmental testing would not cover an important method to detect and respond to identified and suspected food safety problems. Additionally, if food testing does not include environmental testing, our laboratory accreditation program would be unable to accredit laboratories to perform environmental testing or to issue model laboratory standards for environmental testing even though the food testing industry performs both food product tests and environmental tests. We invite comment on this interpretation.

We propose to define ''food testing order'' to mean an order issued by FDA under § 1.1108 of this subpart requiring food testing to be conducted under this program by or on behalf of an owner or consignee. We are proposing specific requirements related to food testing orders in §§ 1.1107, 1.1108, and 1.1174 of this proposed rule.

We propose to define ''owner or consignee'' as any person with an ownership or consignment interest in: The food product or environment that is the subject of food testing conducted under § 1.1107(a)(1); the food product or environment that is the subject of the order issued under § 1.1107(a)(2); the food product or environment that is the subject of food testing conducted under § 1.1107(a)(3); the article of food for which food testing is being conducted under § 1.1107(a)(4); or the food subject to an import alert for which food testing is conducted under § 1.1107(a)(5). Anyone meeting this definition of owner or consignee would be required to use an accredited laboratory to conduct food testing as specified in this proposed rule.

We propose to define ''recognition'' to mean a determination by FDA that an accreditation body meets the applicable requirements of the program and is authorized to accredit laboratories under the program. This definition aligns with the use of the term recognition and ''recognized'' in section 422 of the FD&C Act, which uses these terms to describe the status we will accord to an accreditation body that we have determined meets certain requirements and may therefore accredit laboratories to conduct food testing under this program.

We propose to define ''recognized accreditation body'' to mean an accreditation body that FDA has determined meets the applicable requirements of the program and is authorized to accredit laboratories under the program. As previously discussed, this definition aligns with the use of the term recognition and recognized in section 422 of the FD&C Act, which uses these terms to describe the status we will accord to an accreditation body that we have determined meets certain requirements and may therefore accredit laboratories to conduct food testing under this program. This proposed definition of recognized accreditation body follows from our proposed definitions of recognition and accreditation body.

We propose to define ''representative sample'' to mean ''a sample that accurately, to a scientifically acceptable degree, represents the characteristics and qualities of the food product or environment the sample was collected from.'' If food testing is required to be conducted on a specific food product or environment under this rule, and the sample that is collected from that food or environment is not representative of the food or environment at issue, then analysis of the sample would not produce information that is meaningful. We propose to use the qualifier ''to a scientifically acceptable degree'' because we acknowledge there are practical limits to how accurately a sample can represent the characteristics and qualities of the food product or environment from which it was

collected. Furthermore, what constitutes a representative sample in the context of a certain food product or environment may be a scientific determination that depends on the environment, food matrix, and analyte at issue, among other potential factors. FDA's Investigations Operations Manual, Chapter 4—Sampling, includes some considerations which may inform the identification and collection of a representative sample (*https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual*).

Depending on the food testing to be conducted, it may be appropriate to analyze a single sample that is representative of the food product or environment from which it was collected, to analyze a composite of multiple samples collected from the food product or environment from which it was collected, and/or to analyze a representative sample, taken in the laboratory, of the original representative sample.

We propose to define ''sampler'' as an individual or individuals who perform sampling. The term sampler would refer to single individuals and would not refer to any other type of entity that is treated as a person for certain legal purposes.

We propose to define ''scope of accreditation'' as referring to the methods of analysis for which the accredited laboratory is accredited. We also propose to clarify that references in this rule to accreditation ''in-whole'' refers to all methods in the accredited laboratory's scope of accreditation and accreditation ''in-part'' refers to only certain methods in the accredited laboratory's scope of accreditation. We note that section 7.8 of ISO/IEC 17011:2017 (Ref. 12) requires accreditation bodies to provide information to the laboratories they accredit that identifies their scope of accreditation.

2. Who is subject to this subpart? (Proposed § 1.1103)

The proposed rule would apply to recognized accreditation bodies, entities seeking to become recognized accreditation bodies, accredited laboratories, entities seeking to become accredited laboratories, and owners and consignees who are required to use accredited laboratories for the food testing under this program. Although participation by accreditation bodies and laboratories in this program is voluntary, only accreditation bodies recognized by us under this program would be able to accredit laboratories to conduct food testing under this program, and only laboratories accredited by an accreditation body recognized by us under this program would be able to conduct food testing under this program. However, if finalized, it will not be voluntary for owners and consignees to conduct food testing conducted as described in proposed § 1.1107(a).

B. Proposed Provisions About General Requirements of This Rule (Proposed §§ 1.1107 Through 1.1109)

We have proposed various provisions outlining the general requirements of the food testing program, including when food testing would have to be conducted under this rule, when and how we would issue food testing orders, and how we would make information about recognized accreditation bodies and accredited laboratories available to the public.

1. Under what circumstances must food testing be conducted under this subpart by an accredited laboratory? (Proposed § 1.1107)

Proposed § 1.1107 would require that food testing must be conducted under this rule whenever food testing is conducted by or on behalf of an owner or consignee in any of the following five circumstances: (1) In response to explicit testing requirements (in the FD&C Act or implementing regulations) that address an identified or suspected food safety problem (we elaborate on these explicit corrective action testing requirements below, but, in short, they are located at 21 CFR 112.146(a), (c) and (d), 118.4(a)(2)(iii), 118.5(a)(2)(ii), 118.5(b)(2)(ii), 118.6(a)(2), 118.6(e), and 129.35(a)(3)(i) (regarding the requirement to test five samples from the same sampling site that originally tested positive for *E. coli*)); (2) as required by FDA in a food testing order (issued under § 1.1108 of this rule); (3) to address an identified or suspected food safety problem and presented to FDA as part of evidence for a hearing under section 423(c) of the FD&C Act (21 U.S.C. 350l) prior to the issuance of a mandatory food recall order, as part of a corrective action plan under section 415(b)(3)(A) of the FD&C Act (21 U.S.C. 350d) submitted after an order suspending the registration of a food facility, or as part evidence submitted for an appeal of an administrative detention order under section 304 (h)(4)(A) of the FD&C Act (21 U.S.C. 334(h)(4)(A)); (4) in support of admission of an article of food under section 801(a) of the FD&C Act; and (5) to support removal from an import alert through successful consecutive testing.

a. *Ownership of laboratories that may conduct food testing.*

We note that section 422(b)(1)(A) of the FD&C Act provides that food testing must be conducted under this proposed program whenever food testing is conducted ''by or on behalf'' of an owner or consignee, while section 422(b)(1)(B) of the FD&C Act provides that food testing must be conducted under this rule whenever such testing is conducted on behalf of an owner or consignee in support of admission of an imported article of food and to support removal from an import alert through successful consecutive testing. We tentatively conclude that the ''by or on behalf'' language of section 422(b)(1)(A) of the FD&C Act means that both laboratories owned by owners or consignees and independent, or third-party laboratories, that conduct food testing ''on behalf of'' owners and consignees, must be accredited under this proposed program in order to conduct food testing under section 422(b)(1)(A) of the FD&C Act. Similarly, the ''on behalf of'' language of section 422(b)(1)(B) of the FD&C Act requires independent laboratories to be accredited under this proposed program in order to conduct food testing ''on behalf'' of owners and consignees under section 422(b)(1)(B) of the FD&C Act.

Section 422(b)(1)(B) of the FD&C Act is silent with respect to testing conducted on imports by owners or consignees. Under one possible interpretation, the absence of ''by or'' in this provision would mean that only independent laboratories may be accredited to conduct food testing of imports under section 422(b)(1)(B) of the FD&C Act. Under this interpretation, laboratories owned by owners or consignees would be prohibited from conducting such import-related food testing. Otherwise, such ''in-house'' laboratories would be able to conduct import-related food testing without being accredited through our proposed program, which seems to be contrary to the intent of this program.

Under this interpretation, laboratories owned by owners or consignees would be eligible to conduct food testing under section 422(b)(1)(A) of the FD&C Act but not section 422(b)(1)(B), thereby raising the prospect that section 422(b)(1) would not apply equally to domestic and foreign goods (section 422(b)(1)(A) of the FD&C Act would generally apply to domestic owners or consignees and potentially foreign owners or consignees). Such a difference in treatment could raise potential concerns under U.S. international trade obligations. In this regard, we note that section 404 of FSMA provides that

nothing in the FD&C Act shall be construed in a manner inconsistent with the agreement establishing the WTO or any other treaty or international agreement to which the United States is a party.

In considering section 422(b)(1)(B) of the FD&C Act and section 404 of FSMA together, and to avoid any inconsistency with treaties or international agreements to which the United States is a party, we tentatively conclude that it is reasonable to interpret section 422(b)(1)(B) of the FD&C Act to allow laboratories owned by owners or consignees to conduct food testing that falls under section 422(b)(1)(B) of the FD&C Act, provided that such laboratories meet the accreditation requirements proposed. In addition, we are not aware of information indicating that laboratories owned by owners or consignees of foreign foods are less able to become accredited under this proposed program or to conduct food testing under section 422(b)(1)(B) of the FD&C Act than independent laboratories.

b. *Considerations in interpreting* ''*identified or suspected food safety problem*'' *in section 422(b)(1)(A) of the FD&C Act.*

Section 422(b)(1)(A)(i) and (ii) of the FD&C Act both require, in relevant part, that food testing must be conducted by a laboratory accredited under the food testing program that would be established by this proposed rule, if finalized, when applied to address an identified or suspected food safety problem. Because the circumstances that may constitute a food safety problem are highly fact dependent, we are not proposing an exhaustive list of circumstances that would constitute an ''identified or suspected food safety problem.'' Instead, in proposed § 1.1107(a)(1), we are proposing to codify the circumstances in existing FD&C Act regulations that address an identified or suspected food safety problem and thus trigger the requirement to use an accredited laboratory under this program. We also discuss as part of this rulemaking additional examples of identified or suspected food safety problems to explain the circumstances in which we tentatively conclude would allow for the issuance of food testing orders under proposed § 1.1107(a)(2). In proposed § 1.1107(a)(3) we are proposing to require the use of an accredited laboratory in additional circumstances where FDA determines it is appropriate to address an identified or suspected food safety problem.

The statute does not define the terms ''identified or suspected food safety problem'' or ''food safety problem'' and the term ''food safety problem'' is not used elsewhere in the FD&C Act. However, the section titles of FSMA indicate that ''food safety problems'' are the problems that FSMA is intended to address: Title I of FSMA is entitled ''Improving Capacity to Prevent Food Safety Problems,'' while Title II is entitled ''Improving Capacity to Detect and Respond to Food Safety Problems.'' In the preamble to the preventive controls for human food proposed rule, we noted that food safety problems may be associated with biological, chemical, physical, or radiological hazards (78 FR 3646 at 3667). (We subsequently categorized radiological hazards as a subset of chemical hazards, see 80 FR 55908 at 55950, September 17, 2015).

In considering the circumstances that could constitute an identified or suspected food safety problem, we note that Congress did not require the presence of specific health risks, as in the reasonable probability of serious adverse health consequences or death to humans or animals standard, as a prerequisite to requiring the use of an accredited laboratory under section 422(b)(1)(A) of the FD&C Act. In the preventive controls for human food rule, we indicated that an ''unanticipated food safety problem'' could occur where a preventive control is not properly implemented, including circumstances where a pathogen or appropriate indicator organism is present in a ready-to-eat product detected through product testing, or an environmental pathogen or appropriate indicator organism is detected through environmental monitoring, or where a preventive control is found to be ineffective. See 21 CFR 117.150(b)(1)(i) and (ii) and 117.150(a)(1)(i) and (ii). Depending on the circumstances, we tentatively conclude that a positive indicator organism test would not necessarily constitute even a ''suspected'' food safety problem. For example, because *Listeria* spp. will occasionally be found in a food production environment, our current thinking is that, depending on certain factors, a single positive *Listeria* spp. on a food-contact surface in a facility would not necessarily constitute a suspected food safety problem. We tentatively conclude that an ''identified food safety problem'' could be present when a specific article of food violates a provision of the FD&C Act that relates to food safety, such as certain violations of section 402 of the FD&C Act (21 U.S.C. 342).

Section 422(b)(1)(A) of the FD&C Act does not limit the factors that can generate suspicion of a food safety problem, and we believe a variety of circumstances could generate such suspicion depending on the circumstances, including the presence of *Listeria monocytogenes* on a food-contact surface; the presence of multiple positives for *Listeria* spp. on a food-contact surface; and potential contamination events. We are proposing that the element of suspicion in a ''suspected food safety problem'' typically be particularized, that is, have a basis in fact about a particular article or articles of food (*e.g.,* a lot or batch) or food production environment (*e.g.,* a specific facility), as opposed to being satisfied by the common or usual characteristics of a food (*e.g.,* whether a food is considered ''high-risk'' because of its inherent characteristics, such as pH or water activity) or the manner in which such food is typically produced. Under this proposal, suspicion that a specific article of food violates a provision of the FD&C Act or implementing regulations related to food safety would constitute a suspected food safety problem.

For these reasons, we tentatively conclude that the routine product testing and environmental monitoring requirements at § 117.165(a)(2) and (3), respectively, are not conducted to address a suspected (or identified) food safety problem, because this testing is conducted to verify the implementation and effectiveness of preventive controls and not because a food safety problem is suspected or identified. See 80 FR 55908 at 56062.

Although we are not proposing an exhaustive list of identified or suspected food safety problems, in proposed § 1.1107(a)(1), (a)(2), or (a)(3), we are proposing to codify testing requirements in § 1.1107(a)(1) and (a)(3) that address an identified or suspected food safety problem, which provides examples of circumstances that would constitute an identified or suspected food safety problem.

c. *Proposed § 1.1107(a)(1) and section 422(b)(1)(A)(i) of the FD&C Act.*

Because section 422(b)(1)(A)(i) of the FD&C Act applies to ''specific'' testing requirements, we propose to interpret section 422(b)(1)(A)(i) to apply only to provisions of the FD&C Act or its implementing regulations that explicitly require food testing.

We have identified nine explicit testing requirements in our regulations that we tentatively conclude address an identified or suspected food safety problem. Each of these explicit testing requirements is required as followup, or corrective action, testing after a routine test is positive for a pathogen or indicator organism. Five of these testing requirements are in our regulations on production, storage, and transportation

of shell eggs (specifically, the testing requirements of §§ 118.4(a)(2)(iii), 118.5(a)(2)(ii), 118.5(b)(2)(ii), 118.6(a)(2), and 118.6(e)), three are in our standards for the growing, harvesting, packing, and holding of sprouts (specifically, the testing requirements of § 112.146(a), (c), and (d)), and one is in our regulations on the processing and bottling of bottled drinking water (specifically, one of the testing requirements of § 129.35(a)(3)(i)). More specifically, testing would have to be conducted under this program under proposed § 1.1107(a)(1), if finalized, under the following circumstances:

With respect to production, storage, transportation of shell eggs:

- Section 118.4(a)(2)(iii) requires that if the environmental test required in paragraph (a)(2)(i) of § 118.4 is positive, you must begin egg testing, as specified in § 118.6, within 2 weeks of the start of egg laying.
- Section 118.5(a)(2)(ii) requires that if the environmental test at 40 to 45 weeks is positive, then you must begin egg testing (described in § 118.6), unless you divert eggs to treatment as defined in § 118.3 for the life of the flock in that poultry house. Results of egg testing must be obtained within 10 calendar days of receiving notification of the positive environmental test.
- Section 118.5(b)(2)(ii) requires that if the environmental test at 4 to 6 weeks after the end of a molting process is positive, then you must begin egg testing (described in § 118.6), unless you divert eggs to treatment as defined in § 118.3 for the life of the flock in that poultry house. Results of egg testing, when conducted, must be available within 10 calendar days of receiving notification of the positive environmental test.
- Section 118.6(a)(2) requires that if you have an SE-positive environmental test at any time during the life of a flock, you must divert eggs to treatment (defined in § 118.3) for the life of the flock in that positive poultry house or conduct egg testing as specified in paragraphs (b) through (e) of this section.
- Section 118.6(e) requires that if you have a positive egg test in a flock and divert eggs from that flock and later meet the negative test result requirements described in paragraph (c) of this section and return to table egg production, you must conduct one egg test per month on that flock, using sampling and methodology in §§ 118.7 and 118.8, for the life of the flock.

With respect to our standards for the growing, harvesting, packing, and holding of sprouts:

- Section 112.146 requires that, if you detect *Listeria* species or *L. monocytogenes* in the growing, harvesting, packing, or holding environment you must conduct additional testing of surfaces and areas surrounding the areas where *Listeria* species or *L. monocytogenes* was detected to evaluate the extent of the problem, including the potential for *Listeria* species or *L. monocytogenes* to have become established in a niche; conduct additional sampling and testing to determine whether the *Listeria* species or *L. monocytogenes* has been eliminated; and conduct finished product testing when appropriate.

With respect to the processing and bottling of bottled drinking water:

- Section 129.35(a)(3)(i) requires that a source previously found to contain *E. coli* will be considered negative for *E. coli* after five samples collected over a 24-hour period from the same sampling site that originally tested positive for *E. coli* are tested and found to be *E. coli* negative.

Many explicit testing requirements in our regulations are not subject to section 422(b)(1)(A)(i) of the FD&C Act because they require routine or verification testing, as opposed to testing to address an identified or suspect food safety problem. For example, none of the various testing requirements in our infant formula regulations at 21 CFR part 106 would require the use of an accredited laboratory under this program because they are routine testing requirements for each production aggregate of infant formula manufactured.

Section 422(b)(1)(A)(ii) of the FD&C Act requires, in pertinent part, that food testing must be conducted under this proposed rule whenever food testing is conducted by or on behalf of an owner or consignee as required by the Secretary of HHS, as the Secretary deems appropriate, to address an identified or suspected food safety problem. As such, we are interpreting section 422(b)(1)(A)(ii) of the FD&C Act to give FDA the authority to specify additional circumstances where food testing will be required to be conducted under this program, provided that the food testing is conducted to address an identified or suspected food safety problem. Unlike our authority under section 422(b)(1)(A)(i) of the FD&C Act, which gives us the authority to require food testing to be conducted under this program in response to ''specific testing requirements,'' we are interpreting section 422(b)(1)(A)(ii) to give us authority to require testing to be conducted under this program in the absence of an existing explicit requirement to conduct testing under the FD&C Act or its implementing regulations. Therefore, we are proposing in § 1.1107(a)(2) to require that food testing be conducted under this rule whenever food testing is conducted by or on behalf of an owner or consignee as required by FDA in a food testing order. We explain food testing orders in more detail in section VI.B.2 where we discuss proposed § 1.1108 (which addresses the question of when and how FDA will issue a food testing order).

Proposed § 1.1107(a)(3) would require that food testing be conducted under this program when food testing is conducted to address an identified or suspected food safety problem and presented to FDA as part of evidence for an informal hearing before a mandatory recall order under section 423(c) of the FD&C Act, as part of a corrective action plan under section 415(b)(3)(A) of the FD&C Act submitted after an order suspending the registration of a food facility, or as part of evidence submitted for an appeal of an administrative detention order under section 304(h)(4)(A) of the FD&C Act. Although these three enforcement authorities do not require food testing, if owners and consignees elect to conduct food testing in response to proceedings under these authorities, and such food testing addresses an identified or suspected food safety problem, this proposal would require such food testing to be conducted by a laboratory accredited under this proposed program.

This proposed requirement is authorized under section 422(b)(1)(A)(ii) of the FD&C Act, which states that testing must be conducted under the accredited laboratory program whenever such testing is conducted as required by the Secretary of HHS, as the Secretary deems appropriate, to address an identified or suspected food safety problem. As explained previously in the discussion of food testing orders under proposed section § 1.1107(a)(2), we are interpreting section 422(b)(1)(A)(ii) of the FD&C Act to give FDA the authority to specify additional circumstances where food testing will be required to be conducted under this program in the absence of an explicit requirement to conduct food testing under the FD&C Act or its implementing regulations, provided that the food testing is conducted to address an identified or suspected food safety problem. As such, we are proposing in § 1.1107(a)(3) to require owners or consignees to conduct food testing under this program whenever they elect to conduct food testing under the circumstances specified in § 1.1107(a)(3). We tentatively conclude that it is

appropriate to require food testing related to these important public health enforcement authorities to be conducted under this program because all three of those circumstances could involve situations where food testing might be conducted to address an identified or suspected food safety problem.

Specifically, FDA's mandatory food recall authority gives us the authority to order a responsible party to recall an article of food where we determine that there is a reasonable probability that the article of food (other than infant formula) is adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)) and there is a reasonable probability that the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals. Before such an order is issued, FDA must provide the responsible party with an opportunity to request an informal hearing. Under the provision proposed here, if the results of food testing intended to address an identified or suspected food safety problem are submitted as evidence for the hearing, such tests must be conducted by a laboratory accredited under this program.

Section 415(b)(1) of the FD&C Act provides that if the Secretary of HHS determines that food manufactured, processed, packed, received, or held by a facility registered under section 415 of the FD&C Act has a reasonable probability of causing serious adverse health consequences or death to humans or animals, the Secretary may by order suspend the registration of a facility that: (1) Created, caused, or was otherwise responsible for such reasonable probability or (2) packed, received, or held such food. Section 415(b)(3)(A) of the FD&C Act provides that if, after providing opportunity for an informal hearing, the Secretary of HHS determines that the suspension of registration remains necessary, the Secretary shall require the registrant to submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by the Secretary. We are proposing in § 1.1107(a)(3), that if any such corrective action plan includes food testing to address an identified or suspected food safety problem, such food testing must be conducted by a laboratory accredited under this program.

Under section 304(h) of the FD&C Act, FDA can order administrative detention of food if there is reason to believe that an article of food is adulterated or misbranded. If FDA issues an order to administratively detain food, FDA will provide an opportunity to appeal the detention as specified under section 304(h)(4)(A) of the FD&C Act. We are proposing that if the results of testing intended to address an identified or suspected food safety problem are submitted to appeal the detention, such tests must be conducted by a laboratory accredited under this program. See proposed § 1.1107(a)(3).

Use of a laboratory accredited under this program in the context of these three enforcement authorities will increase our confidence in the food testing conducted in response to identified or suspected food safety problems of great significance to public health. By requiring that food testing be conducted in a manner in which we have added confidence, we will be in a better position to make appropriate decisions that protect public health.

Section 422(b)(1)(B)(i) of the FD&C Act requires, in pertinent part, that food testing must be conducted under the food testing program that would be established by this proposed rule, if finalized, whenever food testing is conducted on behalf of an owner or consignee in support of admission of an article of food under section 801(a) of the FD&C Act (*i.e.,* food that is imported or offered for import into the United States). We are proposing this requirement in § 1.1107(a)(4) of this proposed rule.

As explained in section III.C., under section 801(a)(3) of the FD&C Act, we may refuse admission of an article of food imported or offered for import into the United States if the food is, or appears to be, adulterated or misbranded. Pending our decision to refuse admission, section 801(a) of the FD&C Act allows the owner or consignee of the imported article of food to introduce testimonial evidence regarding the admissibility of the food. Under § 1.94(a), such testimony must be confined to matters relevant to the admissibility or destruction of the article of food and may be introduced orally or in writing.

Owners and consignees often hire private laboratories to test the food and submit to us the results of the testing, along with associated analysis and data, as testimony to establish that the imported food complies with the FD&C Act. Currently, if we determine that the sampling methods and testing results are valid and that they demonstrate the detained food product does not appear to violate the FD&C Act, we will release the food from detention and allow it to proceed into the United States. Again, if this rule is finalized, an owner or consignee whose entry has been detained under 801(a) of the FD&C Act would need to use a lab accredited under this program in order to use the test results as testimonial evidence supporting admission.

We note that to the extent that a question exists as to whether section 422(b)(1)(B)(i) of the FD&C Act applies to food testing to demonstrate compliance with section 805 of the FD&C Act for purposes of supporting admission of an article of food under section 801(a)(3) of the FD&C Act, we tentatively conclude that it does not apply. FSMA amended the FD&C Act to add section 805 to require persons who import food into the United States to perform risk-based foreign supplier verification activities for the purpose of verifying that imported food meets applicable U.S. safety requirements (the FSVP regulation, codified in §§ 1.500 through 1.514, specifies the foods and importers to which the FSVP regulation applies and establishes requirements related to supplier verification). An article of food is subject to refusal of admission under section 801(a)(3) of the FD&C Act if it appears that the importer of the food ''is in violation of such section 805,'' that is, fails to comply with the FSVP regulations with respect to that food. See also § 1.514(a). Significantly, this provision in section 801(a)(3) of the FD&C Act relates to the compliance status of the *importer,* and not the food. Consequently, the relevant inquiry for purposes of this provision of section 801(a)(3) of the FD&C Act is whether an importer has followed FSVP requirements. By contrast, section 422(b)(1)(B)(i) of the FD&C Act relates directly to the compliance status of articles of food.

Given the different focus of the FSVP provision in section 801(a)(3) of the FD&C Act from the focus of section 422(b)(1)(B)(i) of the FD&C Act, we tentatively conclude that it is reasonable to not apply section 422(b)(1)(B)(i) of the FD&C Act to food testing related to FSVP. That is, we tentatively conclude that it is reasonable to not require accredited laboratory to conduct food testing under this program for purposes of the FSVP rule.

Section 422(b)(1)(B)(ii) of the FD&C Act requires that food testing must be conducted under the food testing program that would be established by this proposed rule, if finalized, whenever food testing is conducted on behalf of an owner or consignee to support the removal of food from an import alert through successful consecutive testing. We are proposing this food testing requirement in § 1.1107(a)(5) of this proposed rule.

An import alert conveys evidence that FDA can use to detain, without first

physically examining, incoming products that appear to violate the FD&C Act. The alert communicates that the Agency has enough evidence or other information to refuse admission of future shipments of an imported article, without first physically examining (sampling) the shipments. Put another way, the import alert indicates that there is enough evidence to detain the product without physical examination. There are a variety of factors that could lead FDA to place a product, manufacturer, shipper, grower, geographical area, and/or country on import alert. For example, questions could have been raised in an inspection of the manufacturing site, concerns might be raised by a recall, or there could be a history of problems and no signs that appropriate actions were taken to remedy the cause. In order for FDA to consider removing a product and/or firm from import alert, FDA must have evidence that the conditions that gave rise to the appearance of a violation have been resolved and the Agency has confidence that future entries will be in compliance with FDA laws and regulations. Often, individual import alerts include specific information regarding removal from DWPE. At the present time, many import alerts indicate that it would be helpful for responsible entities to present to FDA evidence of at least five shipments to the United States that have been found to not be violation.

In contrast to section 422(b)(1)(B)(i) of the FD&C Act, which applies exclusively to specific articles of food that are imported or offered for import into the United States, section 422(b)(1)(B)(ii) of the FD&C Act applies to food generally. As such, we tentatively conclude that section 422(b)(1)(B)(ii) of the FD&C Act applies whenever successful consecutive testing supports the removal of food from an import alert, including testing on specific articles of food that are imported or offered for import into the United States and less common situations where food testing is conducted on food that is not being imported or offered for import into the United States. For example, section 422(b)(1)(B)(ii) of the FD&C Act would also apply if the results from successful consecutive testing of environmental swabs or of food that is being imported or offered for import in a foreign country are presented as evidence demonstrating that a manufacturer should be removed from an import alert. At present, most successful consecutive testing conducted for food under an import alert is conducted on specific articles of food that are imported or offered for import into the United States—and thus fall under both sections 422(b)(1)(B)(i) and (ii) of the FD&C Act (and proposed §§ 1.1107(a)(4) and (a)(5)). However, we assume that Congress intended section 422(b)(1)(B)(ii) of the FD&C Act to have an independent meaning. (Norman J. Singer & J.D. Shambie Singer, 1A Sutherland Statutory Construction § 21:1 (7th ed. 2018) which states that ''[c]ourts should construe a statute, if possible, so no term is rendered superfluous or meaningless.'') Therefore, we interpret section 422(b)(1)(B)(ii) of the FD&C Act to apply in part to food testing not covered by section 422(b)(1)(B)(i) of the FD&C Act, including successful consecutive testing for food under import alert that is not conducted on specific articles of food that are imported or offered for import into the United States.

Finally, we note that we are not, as part of this rulemaking, defining the number of successful consecutive tests that would be required or recommended to support removal from import alert. Instead, this proposed rule would require that if you use successful consecutive testing as a means to support removal of food from an import alert, then such testing must be conducted under this program. (For procedural information on removal from DWPE, see section 9–8 of FDA's Regulatory Procedures Manual at *https://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm*.)

In accordance with section 422(b)(1) of the FD&C Act, proposed § 1.1107(b) would require that whenever food testing is required to be conducted in accordance with this program, as described in proposed § 1.1107(a), analysis of the collected samples must be conducted by accredited laboratories that are accredited for the appropriate analytical method or methods by a recognized accreditation body.

Proposed § 1.1107(c) would require, with one exception, that such food testing may only be conducted on samples taken after the articles of food have arrived in the United States. As part of our import admissibility process, this policy allows us to verify that the requirements of § 1.94(a) are met—*i.e.,* that the testimony is relevant to admissibility in that the article(s) of food that is sampled and tested is the same article(s) of food being offered for import into the United States. Importantly, this policy would also help to ensure that the tested sample(s) accurately represents the condition of the article when presented for admission, thereby ensuring the evidence presented by the owner or consignee is representative of the article(s) offered for import. Proper and valid analysis of a sample is not relevant testimony about admissibility if the analyzed sample is not representative of the article of food imported or offered for import into the United States. Based on best available science and grounded in years of experience, we know that the process of getting a food item from where it was produced abroad to a U.S. port of entry is such that change in the item or analyte may occur. For example, bacteria may grow in the time it takes to transport an article of food from the point of export to the United States, or a new contaminant may be intentionally or inadvertently introduced in transit. Accordingly, when specific articles of food are imported or offered for import into the United States, our general policy would be that the sample must be taken after arrival.

We are also proposing, however, an exception to that sampling policy for circumstances in which we determine that a sample taken prior to arrival is representative of the article of food offered for import into the United States and thereby satisfies those evidentiary requirements. We would make such a determination on a case-by-case basis, based on clear evidence that the product sampled and analyzed is actually the product offered for import. We would communicate our determination in writing to the owner/consignee. We invite comment on this proposed exception and whether, in addition to applying the exception on a case-by-case basis, we could extend the exception to apply to a set of defined circumstances. We invite comment on whether there are specific circumstances under which we could make a determination that could be applied broadly, say to a particular commodity or analyte generally, that sampling taken prior to export is representative of the article(s) offered for import? If so, what are those circumstances, and what evidence would give us assurance that sampling of all such articles prior to export would be representative of all articles arriving in the United States?

As discussed above, we are proposing to interpret section 422(b)(1)(B)(ii) of the FD&C Act such that testing conducted under paragraph (ii) (under an import alert that requires successful consecutive tests) would encompass both testing of specific articles of food imported or offered for import and other testing related to an import alert. For import alerts where food product testing

is generally sufficient evidence to overcome the appearance of the violation(s), although at present it is standard practice for a responsible entity seeking to have a food product removed from import alert to submit evidence of at least five non-violative shipments, it is possible that in some circumstances other testing could constitute relevant evidence. Examples of other, potentially relevant, testing might be environmental swabbing of a production facility, or food testing unconnected to a shipment of food offered for import into the United States. Our proposed sampling policy in § 1.1107(c) would not apply to testing under an import alert that is unrelated to articles of food offered for import, because in circumstances unrelated to shipments, transit and timing issues would not present likely barriers to the relevance of the testing evidence.

2. When and how will FDA issue a food testing order? (Proposed § 1.1108)

Proposed § 1.1108 would, if finalized, establish our procedure for issuing food testing orders. Specifically, proposed § 1.1108(a) provides that we may require an owner or consignee of an article of food to conduct food testing, or to have food testing conducted on their behalf, under this program, to address an identified or suspected food safety problem related to the article of food. As described previously, our authority for proposed § 1.1108 comes from section 422(b)(1)(A)(ii) of the FD&C Act, which provides that food testing must be conducted under the food testing program described in section 422 of the FD&C Act, whenever such testing is conducted by or on behalf of an owner or consignee, as required by FDA, as FDA deems appropriate, to address an identified or suspected food safety problem.

Proposed § 1.1108(b) elaborates that the food testing order will specify the food product or environment to be tested; whether the food testing may be conducted using an accredited laboratory that is owned, operated, or controlled by the owner or consignee; the timeframe in which the food testing must be conducted; and the manner of the food testing, such as the methods that must be used. We tentatively conclude that the language in section 422(b)(1)(A)(ii) of the FD&C Act stating that food testing must be conducted as required by FDA and as FDA deems appropriate grants FDA discretion to specify the terms and conditions of a food testing order to address an identified or suspected food safety problem.

Proposed § 1.1108(c) provides that food testing orders would contain all of the elements required by 21 CFR 16.22(a) and would thereby constitute notice of an opportunity for a regulatory hearing under 21 CFR part 16. Proposed § 1.1108 further provides that an affected owner or consignee would be able to request a regulatory hearing on a food testing order under proposed § 1.1174.

3. How will FDA make information about recognized accreditation bodies and accredited laboratories available to the public? (Proposed § 1.1109)

Proposed § 1.1109 provides that (except as provided by proposed § 1.1109(b), which we discuss below) we would place on our website a list, which would be readily accessible to the public, of recognized accreditation bodies and accredited laboratories in the food testing program. We would establish and display this list in accordance with section 422(a)(1)(B) of the FD&C Act, which requires us to establish a publicly available registry of accreditation bodies recognized by FDA and laboratories accredited by a recognized accreditation body, including the name of, contact information for, and other information deemed appropriate by the FDA about such bodies and laboratories.

The proposed list would include the name of and contact information for each recognized accreditation body and accredited laboratory in our program. We propose that it is also appropriate for the list to include, for each recognized accreditation body, the duration of the recognized accreditation body's recognition, and, for each accredited laboratory, the scope of accreditation, as well as the name and contact information of the recognized accreditation body that accredited the accredited laboratory. We also propose that the list include the recognition status of each accreditation body that has been recognized (*i.e.,* whether the accreditation body's recognition is active, or whether it has been put on probation or revoked by FDA, relinquished by the accreditation body, or allowed to expire by the accreditation body), the date of any such change in recognition status, the accreditation status of each laboratory that has been accredited (*i.e.,* whether the laboratory's accreditation is active, or whether the laboratory's accreditation is withdrawn or revoked or it has been put on probation by a recognized accreditation body or FDA (including whether by FDA or by a recognized accreditation body), or the laboratory has relinquished its accreditation (in-whole or in-part)), and the date of any such change in accreditation status.

We believe this additional information beyond the name and contact information of recognized accreditation bodies and accredited laboratories would be appropriate to include in the list because it would make the list more useful and increase transparency. For example, if we did not include information about whether an accreditation body had its recognition revoked by FDA, and we instead simply deleted the accreditation body from the list, there could be ambiguity with respect to whether the deletion was for cause or whether the accreditation body voluntarily relinquished its recognition. We believe that users of the list would find the distinction between those two alternatives to be important. In addition, if a laboratory voluntarily relinquished its accreditation in-part, it might want the list to make clear that the reduction in its scope of accreditation was a voluntary action.

Proposed § 1.1109(b) reiterates section 422(a)(4) of the FD&C Act, which grants us the authority to, when in the interest of national security, determine in coordination with the Secretary of Homeland Security the time, manner, and form in which the list described in proposed § 1.1109(a) is made publicly available. In the absence of a determination to the contrary under proposed § 1.1109(b), the list would remain publicly and readily available at all times on our website and display all information specified by proposed § 1.1109(a).

C. Proposed Provisions About Recognition of Accreditation Bodies (Proposed § 1.1113)

Section 422(a)(2) of the FD&C Act requires that FDA provide for the recognition of laboratory accreditation bodies that meet the criteria established by FDA for accreditation of laboratories to conduct food testing. Accordingly, this proposed rule proposes certain criteria that accreditation bodies must meet to become recognized by FDA to accredit laboratories under this program.

1. What requirements must an accreditation body meet to be recognized by FDA? (Proposed § 1.1113)

Proposed § 1.1113 would require that, to become recognized by FDA, an accreditation body seeking recognition by FDA must: (a) Be a full member of ILAC and a signatory to the ILAC MRA that has demonstrated competence to ISO/IEC 17011:2017; (b) demonstrate it meets the requirements of ISO/IEC 17011:2017 (Ref. 12); (c) demonstrate

that it possesses sufficient scientific/technical expertise to be able to substantively assess certain work of the laboratories it accredits; and (d) demonstrate it is capable of complying with this rule's proposed requirements for recognized accreditation bodies.

ILAC was established to create an international arrangement between member accreditation bodies to develop and harmonize laboratory and inspection body accreditation practices. Currently more than 90 accreditation bodies are signatories to the ILAC MRA. To become an ILAC MRA signatory, an accreditation body must commit itself to maintaining conformity with the current version of ISO/IEC 17011 and to ensuring that all laboratories it accredits comply with appropriate laboratory standards. Under this proposed rule, accreditation bodies would be required to meet ISO/IEC 17011:2017, which is incorporated by reference. Therefore, we are proposing that in order to be recognized as an accreditation body, an accreditation body must be a signatory to the ILAC MRA that has demonstrated competence to ISO/IEC 17011:2017. If at some point in the future ISO/IEC 17011:2017 is updated, FDA would consider whether to amend the codified consistent with that update, allowing an adequate transition period.

Requiring recognized accreditation bodies to be signatories to the ILAC MRA that have demonstrated competence to ISO/IEC 17011:2017 and to be members in good standing of ILAC would also be consistent with our withdrawn 2009 draft guidance, in which we recommended that accredited laboratories be ILAC MRA signatories. We also considered the rationale stated by the Consumer Product Safety Commission (CPSC) in its 2013 rule, ''Requirements Pertaining to Third Party Conformity Assessment Bodies'' (78 FR 15836, March 12, 2013), for requiring accreditation bodies to be signatories to the ILAC MRA. In particular, we agree with CPSC that requiring accreditation bodies to be signatories to the ILAC MRA that have demonstrated competence to ISO/IEC 17011, and not accepting any other arrangement, would: (1) Keep the accreditation program as simple as possible for use by interested parties (in our case, owners and consignees, accreditation bodies, and laboratories); (2) avoid any perceived notions of barriers to fair trade practices; establish a program that is manageable within Agency resources; and (3) maintain consistency in the procedures used by the recognized accreditation bodies (see 78 FR 15836 at 15857).

Proposed § 1.1113(b) would require that, to become recognized by FDA, an accreditation body seeking recognition by FDA must demonstrate that it meets the requirements of ISO/IEC 17011:2017. ISO/IEC 17011:2017 specifies the general requirements for accreditation bodies assessing and accrediting conformity assessment bodies (''conformity assessment bodies'' are organizations providing testing, inspection, management system certification, personnel certification, or product certification). ISO/IEC 17011 is widely accepted, both domestically and internationally, and its incorporation by reference should allow us to utilize a framework that is familiar to accreditation bodies and the food industry.

Proposed paragraph (c) would require that to be recognized under this program, an accreditation body must possess certain scientific/technical expertise. Because the food testing that occurs under this program is important to public health, the laboratories conducting these food tests must be able to properly and accurately apply a particular test method, in an appropriate circumstance. Thus, it is vital that test methods be validated [6] and verified as necessary (see § 1.1151(a)), and that laboratories demonstrate their capability by participating in comparison programs such as proficiency testing (see § 1.1138(a)(1)(ii)). Under this proposed rule, we would be relying on recognized accreditation bodies to substantively review some validation and verification studies, as well as accredited laboratories' proposed alternatives to proficiency tests, as part of their consideration of whether laboratories are competent to conduct the test methods for which they are seeking accreditation (see § 1.1138(a)(1)). Thus, we would expect recognized accreditation bodies to serve a function that accreditation bodies have not traditionally performed.

Accordingly, to be recognized in this program, we expect an accreditation body to be able to substantively review validation studies; to have the scientific knowledge to meaningfully assess whether a study indicates that a proposed test method detected the identified hazard (or analyte) with sufficient accuracy and precision. We would expect recognized accreditation bodies to assess verification studies to determine whether the test method at issue may be properly applied to a particular food/analyte combination (*e.g.,* strawberries/*salmonella*). We would also expect recognized accreditation bodies to be able to assess an accredited laboratory's determination under proposed § 1.1148(a)(2) that no proficiency testing program is available or practicable for a particular method, and to be able to assess whether a proposed alternative to a proficiency test would adequately demonstrate the laboratory's competence to conduct a test method. In these ways, we would expect accreditation bodies to possess and apply substantive scientific/technical knowledge. We acknowledge that for most if not all accreditation bodies, obtaining such scientific knowledge will require either hiring qualified in-house staff or contracting with assessors with the necessary experience and expertise. We have accounted for that cost in our proposed regulatory impact analysis.

Again, this function of a recognized accreditation body is important to the public health, and we plan to robustly monitor this aspect of their performance. To that point, we intend to communicate our expectations for the assessment of validation and verification studies, and alternatives to proficiency tests, to the recognized accreditation bodies. We may consider issuing guidance on this topic, making ourselves available for technical assistance such as via regular roundtable meetings/conference calls with recognized accreditation bodies, and we welcome suggestions of other measures we could employ to support the recognized accreditation bodies in this function. We also welcome comments on this proposed provision.

Proposed § 1.1113(d) provides that an accreditation body seeking recognition must demonstrate it is capable of complying with this subpart's requirements for recognized accreditation bodies, which refers in part to requirements that are specific to this program and not contained in ISO/IEC 17011:2017. These requirements are primarily specified by proposed §§ 1.1119 through 1.1125. For example, those proposed requirements specify that before we will recognize an accreditation body, it must demonstrate to us that it has policies, standard operating procedures, and other appropriate programs and measures in place to meet the proposed impartiality and conflict of interest requirements of proposed § 1.1119 and to make appeals

[6] The terms validate, validation, verify, and verification are used in this proposed rule in the specific context of conducting food testing. Other rules we have issued, particularly some rules we have issued pursuant to FSMA, use one or more of these terms in other contexts. The terms validate, validation, verify, and verification, as used in contexts other than the context of conducting food testing, may have different meanings than they do in the context of this proposed rule.

procedures publicly available in accordance with proposed § 1.1121.

Another example of how paragraphs (b) and (d) of proposed § 1.1113 interact involves certain recordkeeping requirements of ISO/IEC 17011:2017 and additional recordkeeping requirements for recognized accreditation bodies under this proposed rule. ISO/IEC 17011:2017 (Ref. 12) section 9.4.2 requires accreditation bodies to have in place procedures by which records are retained for whatever period of time comports with the accreditation bodies' contractual duties, and proposed § 1.1124 would require that recognized accreditation bodies electronically maintain, for 5 years after the date of creation of the records, records created while they are recognized. Accordingly, under proposed § 1.1113(b) and (d) and § 1.1124, an accreditation body seeking recognition would have to demonstrate the capability to implement records procedures to retain records for a period consistent with its contractual and legal obligations, which would include an obligation under proposed § 1.1124 to maintain certain records, for at least 5 years after the date of creation of the records, created while the accreditation body is recognized.

We discuss the documentation needed to meet the requirements of proposed § 1.1113(a)–(d) where we discuss proposed § 1.1128, below.

We invite comment on proposed § 1.1113's requirements for an accreditation body to become recognized under this program. If comments opposing these proposed requirements are submitted, we request comment on what alternative requirements or qualifications an accreditation body should have to be eligible for recognition to accredit laboratories under this program.

D. Proposed Provisions About Requirements for Recognized Accreditation Bodies (Proposed §§ 1.1118 Through 1.1125)

Section 422 of the FD&C Act provides that food testing under this program may only be conducted by laboratories accredited by accreditation bodies that we have recognized. Section 422(a)(2) of the FD&C Act directs us to establish the criteria for recognition of accreditation bodies and section 422(a)(7)(B) directs us to promptly revoke the recognition of any accreditation body found not to be in compliance with the requirements of section 422 of the FD&C Act. Accordingly, this proposed rule would establish certain criteria and obligations that recognized accreditation bodies must continue to meet to remain recognized. We have proposed these general requirements for recognized accreditation bodies to remain recognized at §§ 1.1118 through 1.1125, and we discuss these requirements below.

1. What are the general requirements for recognized accreditation bodies to remain recognized? (Proposed § 1.1118)

For recognized accreditation bodies to remain recognized, proposed § 1.1118 would require them to continue to: (a) Be a full member of the ILAC and a signatory to the ILAC MRA that has demonstrated competence to ISO/IEC 17011:2017; (b) meet, with respect to activities under this subpart, the requirements of ISO/IEC 17011:2017, which would be incorporated by reference under this rule; (c) demonstrate that it possesses sufficient scientific/technical expertise to be able to substantively assess certain work of the laboratories it accredits; and (d) comply with the proposed requirements for recognized accreditation bodies. The additional requirements referenced by proposed § 1.1118(d) are primarily specified by proposed §§ 1.1119 through 1.1125. See our discussion at section VI.C, above, for more information about these proposed criteria.

2. What requirements apply to how a recognized accreditation body must protect against conflicts of interest? (Proposed § 1.1119)

We believe that protecting against conflicts of interest among participants in this program is critical to the integrity of this proposed program. We are proposing that recognized accreditation bodies take certain steps to safeguard against conflicts of interest in addition to meeting the impartiality requirements of ISO/IEC 17011:2017. Under proposed § 1.1119(a)(1), a recognized accreditation body would need to ensure that it, and its officers, employees, or other agents involved in accreditation activities, does not own or have a financial interest in, manage, or otherwise control any laboratory (or any affiliate, parent, or subsidiary) it accredits. Section 4.4.11 of ISO/IEC 17011:2017 (Ref. 12) prohibits an accreditation body from offering or providing any food testing services (and from offering or providing any other services that may affect its impartiality). However, we have tentatively concluded that it is also important to prevent a recognized accreditation body from having a financial interest in, managing, or otherwise controlling any laboratory (or any affiliate, parent, or subsidiary) that it accredits, and to explicitly extend that prohibition to officers, employees, and other agents of the recognized accreditation body, in order to protect against conflicts of interest. To ensure the effectiveness of proposed § 1.1119(a)(1), we also have tentatively concluded that it is important to extend the conflict of interest safeguards in this provision to subsidiaries, affiliates, and parent organizations of the laboratory. We seek comments with regards to whether proposed § 1.1119(a)(1) would impose an undue burden on any existing financial, managerial, or control interest that accreditation bodies may currently have in food testing laboratories and/or whether there are other measures that could prevent such an interest from creating a conflict of interest.

Under proposed § 1.1119(a)(2), a recognized accreditation body would be required to prohibit officers, employees, or other agents involved in accreditation activities of the recognized accreditation body from accepting any money, gift, gratuity, or other item of value from any laboratory that they accredit or that are seeking their accreditation that conducts food testing. We seek comment on whether this proposal is sufficient to protect against conflicts of interest related to money, gifts, gratuity, and other items of value.

Proposed § 1.1119(b) provides that the prohibited money, gift, gratuity, or other item of value described by proposed § 1.1119(a)(2) does not include payment of fees for accreditation services, reimbursement of direct costs associated with an onsite assessment or reassessment of the laboratory, and onsite lunch, of a de minimis value, provided during the course of an assessment or reassessment, if necessary to facilitate the efficient conduct of the assessment.

Under proposed § 1.1119(c), the financial interests of spouses and children younger than 18 years of age would be imputed to a recognized accreditation body's officers, employees, and other agents involved in its accreditation activities. We have included a similar imputation provision in other regulations, including the FSMA accredited third-party certification regulation. See 21 CFR 1.657(c)) and 21 CFR 516.141(g). We believe this provision would help ensure the integrity of the food testing program.

We seek comment on proposed § 1.1119 and whether there are any other potential conflicts interest for recognized accreditation bodies that should be addressed in this proposed program. For any comment recommending that we address other types of conflicts, we request

recommended measures to address such conflicts, and any references or documents that are available to support the recommendation.

3. How must a recognized accreditation body evaluate laboratories seeking accreditation and oversee the performance of laboratories it accredits? (Proposed § 1.1120)

We anticipate that many laboratories that seek accreditation in our proposed program already will be accredited to ISO/IEC 17025:2017 by an accreditation body to which we have granted recognition. To provide flexibility to such participants, we are proposing laboratory assessment requirements for our program that build upon, and could be combined with, the existing assessments of laboratories that accreditation bodies conduct under ISO/IEC 17011:2017 during an accreditation cycle. For example, if an accreditation body has conducted an onsite assessment of an ISO/IEC 17025:2017 accredited laboratory in the past 2 years, proposed § 1.1120(c) would potentially allow the initial assessment for accreditation to our program to be conducted remotely, and to only address whether the laboratory meets the unique requirements of our program that are not required by ISO/IEC 17025:2017 (see proposed § 1.1138(a)(1) and (c)). If such an onsite assessment has not been conducted in the past 2 years, an accreditation body's initial assessment of a laboratory for accreditation in our program would be required to be conducted onsite and would be required to address whether the laboratory meets all the requirements of our program, including the requirements of ISO/IEC 17025:2017 specified in proposed § 1.1138(a)(2) and (b).

Where the initial assessment for accreditation to our program is conducted remotely under proposed § 1.1120(c), proposed § 1.1120(e) and (f) would require the recognized accreditation body to conduct its first assessment of the sample of the scope of accreditation of the accredited laboratory onsite, and no later than 2 years after the accreditation body last conducted an onsite assessment of the laboratory, in accordance with ISO/IEC 17011:2017. These proposed requirements are intended to ensure that recognized accreditation bodies conduct onsite assessments of accredited laboratories in our program at least every 2 years. We regard periodic onsite assessments as necessary to effectively evaluating a laboratory. In addition, proposed § 1.1120(g) would require that the reassessment of an accredited laboratory (see ISO/IEC 17011:2017 (Ref. 12, at section 7.9.4)) at the end of the laboratory's accreditation cycle be conducted onsite.

However, when conducting an ''onsite'' assessment, if conducting a particular assessment activity onsite will not aid in the assessment of a laboratory, proposed § 1.1120(b), (e), and (g), would allow such activities to be conducted remotely. Our intent is that this exception would allow assessment activities such as document review or followup inquiries to a laboratory after an onsite visit to be conducted remotely. Proposed § 1.1120(h) would allow any assessments conducted by a recognized accreditation body other than the assessments referred to in § 1.1120(a), (e), and (g)—that is, the initial assessment, sample of the scope of accreditation, and reassessment—to be conducted entirely remotely if it will not aid the assessment to conduct them onsite.

4. What appeal procedures must a recognized accreditation body provide for appeals of decisions to not grant accreditation? (Proposed § 1.1121)

Proposed § 1.1121 provides that a laboratory may appeal a decision by the recognized accreditation body to not grant the accreditation (in-whole or in-part) that the laboratory sought, and the recognized accreditation body must consider the appeal, in accordance with the requirements of § 1.1118(b). We are proposing this provision because ISO/IEC 17011:2017 does not explicitly state what actions by the accreditation body a laboratory may appeal.

Proposed § 1.1121 would require recognized accreditation bodies to establish and implement certain written procedures for addressing appeals from laboratories challenging a recognized accreditation body's decision to not grant the accreditation (in-whole or in-part) that the laboratory sought. Specifically, proposed § 1.1121 provides that, in addition to meeting the requirements of § 1.1118(b) related to appeals, the recognized accreditation body must establish and implement written procedures to make the appeals procedures publicly available, and use a competent person(s), who may or may not be external to the recognized accreditation body, is free from bias or prejudice and has not participated in the accreditation decision, and is not the subordinate of a person who participated in the accreditation decision, to review and decide appeals. We have tentatively concluded that the requirements of proposed § 1.1121 are important supplemental requirements to ISO/IEC 17011:2017 (Ref. 12) section 7.13 that would provide additional protections to laboratories and help ensure transparency of the program. We seek comments on these proposed requirements, including with respect to whether these proposed requirements would significantly differ from the current appeals practices of accreditation bodies.

5. When must a recognized accreditation body withdraw or reduce the scope of the accreditation of a laboratory, and when may a recognized accreditation body put an accredited laboratory on probation? (Proposed § 1.1122)

Proposed § 1.1122(a) would require recognized accreditation bodies to withdraw the accreditation of a laboratory it accredits when the accredited laboratory substantially fails to comply with this rule. Although section 7.11 of ISO/IEC 17011:2017 (Ref. 12) specifies certain circumstances that would require the accreditation body to initiate the process for withdrawing the accreditation of the laboratory—including fraudulent behavior—it does not articulate a general standard for when accreditation bodies should initiate the process for withdrawing accreditation.

Although we are proposing that withdrawal of accreditation be initiated by a ''substantial'' failure to comply with this subpart—and not by minor or de minimis violations—we note that the failure or refusal by the accredited laboratory to take appropriate corrective action (as it is required to do under ISO/IEC 17025:2017 (Ref. 13) at section 8.7) to prevent subsequent minor violations may rise to the level of substantial failure to comply with this rule. For example, if on a single occasion an accredited laboratory fails to provide FDA with documentation of the sampler's qualifications as required by § 1.1152(c)(2), that in and of itself would not generally be considered a substantial violation. However, frequent and recurring failure by a laboratory to submit all required components of a full analytical report, even when each instance constitutes a minor violation, combined with a failure or refusal by the accredited laboratory to take appropriate corrective action to prevent such mistakes from recurring, may in certain circumstances be grounds for withdrawal of accreditation.

Proposed § 1.1122(b) provides that a recognized accreditation body may put an accredited laboratory it accredits on probation if the recognized accreditation body determines that the laboratory demonstrates deficiencies in performing

its functions under this program that are less serious than would justify withdrawal of the accredited laboratory's accreditation (in-whole or in-part) under proposed § 1.1122(a), and it is reasonably likely that the accredited laboratory will be able to correct such deficiencies within a reasonable specified period of time. Our intent is that probation would allow recognized accreditation bodies to work with laboratories they accredit to bring such laboratories into compliance with the program without having to resort to withdrawing accreditation.

As noted, this proposed rule refers to reduction of an accredited laboratory's scope of accreditation by a recognized accreditation body as withdrawal of accreditation in-part. Proposed § 1.1122(c) clarifies that when there are grounds for withdrawal of accreditation, but the deficiencies affect only certain analytical methods within the accredited laboratory's scope of accreditation, the recognized accreditation body may withdraw the accredited laboratory's scope of accreditation for only those affected analytical methods. This provision is meant to facilitate limited withdrawal of accreditation when warranted.

Under proposed § 1.1122(d) a recognized accreditation body may require from a laboratory that it accredits the submission of records that the accredited laboratory would be required to maintain under proposed § 1.1153, in order to assist the recognized accreditation body in determining whether a withdrawal of accreditation (in-whole or in-part) or probation is warranted.

Proposed § 1.1122(e) describes the process a recognized accreditation body must follow when withdrawing the accreditation of an accredited laboratory under this program. Under proposed § 1.1122(e), the recognized accreditation body must notify the laboratory of the withdrawal of the laboratory's accreditation, and the notification must specify whether the withdrawal of accreditation is in-whole or in-part, and if it is in-part, to which testing methods it applies. The notification must also describe the grounds on which the accreditation was withdrawn and state the procedures for appealing the withdrawal.

Proposed § 1.1122(f) provides that the recognized accreditation body would have to: (1) Notify the laboratory of its probationary status; (2) describe the grounds for the probation; (3) identify all deficiencies that the laboratory must correct for the recognized accreditation body to lift the probation; and (4) either inform the laboratory that it has a specific timeframe to take particular corrective actions with respect to the identified deficiencies or require the laboratory to submit a plan to the recognized accreditation body for approval that identifies the appropriate corrective actions the laboratory will take to resolve the identified deficiencies and that identifies appropriate timeframes for resolution. Our intent is that while probation is in effect, the recognized accreditation body will work with the accredited laboratory to bring it into compliance with the requirements of the program.

Proposed § 1.1122(g) describes the consequences of withdrawal of accreditation (in-whole or in-part) or probation. If a recognized accreditation body withdraws the accreditation of a laboratory in-whole, the laboratory would be immediately ineligible to conduct food testing under this rule. If the recognized accreditation body withdraws the accreditation of a laboratory in-part, the laboratory would be immediately ineligible to conduct food testing under this rule with respect to only the specific methods for which accreditation was withdrawn. An accredited laboratory's substantial failure to comply with this rule would undermine the integrity and validity of this proposed program and of the laboratory's affected food testing conducted under this proposed rule. Withdrawal of the laboratory's accreditation would ensure that the laboratory does not continue to conduct the affected food testing under this rule. This consequence is in accordance with the requirement in section 422(b)(1) of the FD&C Act that food testing under section 422 may only be conducted by laboratories that are accredited by recognized accreditation bodies for the methods of analysis appropriate for such food testing. An accredited laboratory that is put on probation by an accreditation body under this proposed rule would be permitted to continue to conduct food testing under this subpart, because it would still be accredited under this program. However, an accredited laboratory that is put on probation under this proposed rule would not be able to submit abridged analytical reports under § 1.1152(d).

Proposed § 1.1122(h) discusses requirements related to how the recognized accreditation body must handle appeals of withdrawals of accreditation (in-whole or in-part). Under proposed § 1.1122(h), a laboratory may appeal a decision by the recognized accreditation body to withdraw the accreditation (in-whole or in-part) of the laboratory, and the recognized accreditation body must consider the appeal in accordance with the requirements of ISO/IEC 17011:2017 (Ref. 12) (specifically, ISO/IEC 17011:2017 at section 7.13). In addition to meeting the requirements of ISO/IEC 17011:2017 related to appeals, the recognized accreditation body must establish and implement written procedures to make the appeals procedures publicly available; and to use a competent person(s), who may or may not be external to the recognized accreditation body, who is free from bias or prejudice and has not participated in the withdrawal decision, and is not the subordinate of a person who participated in the withdrawal decision, to review and decide appeals.

6. What reports and notifications must a recognized accreditation body submit to FDA? (Proposed § 1.1123)

Proposed § 1.1123 would require recognized accreditation bodies to submit to FDA reports of their internal audits and notices of matters affecting their recognition and the accreditation status of laboratories they accredit, among other notices.

In proposed § 1.1123 and other provisions in this proposed rule, we are proposing that information submitted to FDA be submitted electronically and in English. Electronic submission of information will help ensure we have ready access to information needed for monitoring and oversight of the program and promote the overall efficiency of the program. We have also tentatively concluded that requiring electronic submission would not be significantly burdensome for the accreditation bodies and laboratories in this program. FDA plans to establish an electronic portal for this program and recognized accreditation bodies would be able to submit all required notification and reports through that portal.

Proposed § 1.1123(a) would require all reports and notifications submitted to FDA under this proposed section to include contact information for the accreditation body associated with the report or notification and, if applicable, contact information for the laboratory associated with the report or notification. Proposed § 1.1123(b) would require recognized accreditation bodies to submit to FDA electronically, in English, a report of the results of the internal audit required by section 9.7 of ISO/IEC 17011:2017 (Ref. 12) and the results of the audit of its compliance with the requirements of § 1.1118(c) and (d), which would be required by proposed § 1.1125, no later than 45 days after completing the internal audit. Proposed § 1.1123(b) further provides that the report of the recognized

accreditation body's internal audit must include a description of the internal audit conducted; a description of any identified deficiencies; a description of any corrective actions taken and any corrective action the recognized accreditation body will take, including the timeline for such corrective actions; and a statement disclosing the extent to which the internal audit was conducted by personnel different from those who perform the activity or activities that were audited. The report does not have to be the same report used internally by the recognized accreditation body, but must be comprehensive enough to demonstrate whether the accreditation body is complying with the requirements of ISO/IEC 17011:2017 and the requirements of § 1.1118(c) and (d). Such reports would provide us with important information about the extent to which the recognized accreditation body is monitoring its own performance under this program, any deficiencies the recognized accreditation body discovered about its activities, and any corrective actions implemented to address such deficiencies.

Because recognized accreditation bodies must conduct such internal audits under ISO/IEC 17011:2017 and to maintain their ILAC membership, proposed § 1.1123(b) would not require the recognized accreditation body to engage in duplicative internal audits. We also believe that providing 45 days for the recognized accreditation body to compile and submit this report is a reasonable amount of time that strikes a balance between our interest in reviewing information that is important to our oversight of the program and providing the recognized accreditation body sufficient time to initiate any appropriate corrective actions and develop a meaningful internal audit report. If the internal audit results in the recognized accreditation body discovering information that must be submitted to FDA immediately under proposed § 1.1123(c), we expect the recognized accreditation body to submit that particular information to us immediately, within 48 hours, in accordance with proposed § 1.1123(c).

Section 422(a)(1)(C) of the FD&C Act requires, as a condition of recognition, that recognized accreditation bodies report to us any changes that would affect the recognition of such recognition body. To implement this provision, proposed § 1.1123(c)(1) would require the recognized accreditation body to notify us immediately of any changes it is aware of that would affect its recognition, including a description of the change, and, if the change is one made by the recognized accreditation body, an explanation for the purpose of the change. Proposed § 1.1123(c)(1) would cover changes in the name or operations of a recognized accreditation body, such as the purchase of a recognized accreditation body by a company, as well as changes that would cause the recognized accreditation body to no longer meet the requirements of this proposed program, including if the recognized accreditation body ceases membership in ILAC or is no longer a signatory of the ILAC MRA demonstrating competence to ISO/IEC 17011:2017. A change that prevents or undermines the accreditation body's compliance with this proposed program may result in revocation of recognition under proposed § 1.1131. We would encourage recognized accreditation bodies to contact us if there are uncertainties about whether a change should be reported under proposed § 1.1123(c)(1).

Proposed § 1.1123(c)(2) through (6) would require recognized accreditation bodies to immediately notify us, within 48 hours, of certain information related to the accreditation status of laboratories they accredit or that have sought their accreditation. Immediate notice is essential so that we can take timely action to update the public website described by proposed § 1.1109; accept food testing results from newly accredited laboratories; refuse to accept food testing results from laboratories that are no longer accredited for the food testing at issue; and take any other actions as appropriate based on such information.

Proposed § 1.1123(c)(2) and (3) would require recognized accreditation bodies to submit information to us about their grants and denials of accreditation (in-whole or in-part) of laboratories. If a recognized accreditation body received a request for accreditation (which includes a request from a laboratory to add testing methods to its scope of accreditation) from a laboratory, and the recognized accreditation body granted accreditation for certain testing methods in the laboratory's request but denied accreditation for other testing methods in the laboratory's request, proposed § 1.1123 would only require that a recognized accreditation body provide us with a single notification encompassing this information, as long as the notification includes all of the information that would be required under proposed § 1.1123(c)(2) and (3).

Proposed § 1.1123(c)(2) and (3) would require the notification to include the scope of accreditation requested by the laboratory, the scope of accreditation granted and/or denied, and the ground for such denial, and the date of such grant. This information would be useful for our program oversight. For example, it would allow us to monitor accreditation activities, including situations where a laboratory appears to be successively applying for, and being denied, accreditation from different recognized accreditation bodies without changing its practices or application to remedy the basis or bases for the previous denial(s).

Proposed § 1.1123(c)(4) would require a recognized accreditation body to notify us immediately if it receives notice that an accredited laboratory it accredits intends to relinquish its accreditation (in-whole or in-part). Proposed § 1.1123(c)(4) would also require such notification to include the scope of accreditation to which the relinquishment applies, and the effective date of the relinquishment.

Proposed § 1.1123(c)(5) would require a recognized accreditation body to notify us immediately when it withdraws (in-whole or in-part) its accreditation of a laboratory. Proposed § 1.1123(c)(5) would also require such notification to include the scope of accreditation to which the withdrawal applies, and the grounds for the withdrawal.

Proposed § 1.1123(c)(6) would require a recognized accreditation body to notify us immediately when it puts an accredited laboratory on probation. Proposed § 1.1123(c)(6) would also require such notification to include the grounds for the probation, and any date by which the recognized accreditation body has determined the accredited laboratory must take appropriate corrective action.

Having information on the reason(s) for probation or withdrawal of accreditation, and whether such withdrawal is in-whole or in-part, is important to us because it may affect whether and how we conduct any followup actions with regards to the laboratory in question or how we review food testing results from the laboratory in the future.

Proposed § 1.1123(c)(7) would require recognized accreditation bodies to notify us immediately when the recognized accreditation body knows that an accredited laboratory it accredits has committed fraud or submitted material false statements to FDA. We note that we would also typically expect the recognized accreditation body to initiate its process to withdraw accreditation of the laboratory in this circumstance (in accordance with ISO/IEC 17011:2017 (Ref. 12) section 7.11.2). Proposed § 1.1123(c)(7) would require the notification to include a description

of the basis for the accreditation body's knowledge of the fraud or material false statements, a description of the alleged fraud or material false statements, and the actions taken by the accreditation body with respect to such laboratory. Recognized accreditation bodies may be in a better position than us in many cases to determine whether an accredited laboratory has committed fraud or submitted material false statements to the FDA, due to recognized accreditation bodies' role in monitoring the laboratories they accredit. Furthermore, although proposed § 1.1152(j) would require accredited laboratories to immediately notify us of any changes that would affect an accredited laboratory's compliance with the program requirements or that would otherwise affect the laboratory's accreditation, an accredited laboratory that has committed fraud or submitted material false statements to us may be unlikely to notify us that it did so.

7. What records requirements must a recognized accreditation body meet? (Proposed § 1.1124)

This proposed rule identifies specific types of records a recognized accreditation body would be required to control and maintain to document compliance with applicable requirements. The recognized accreditation body also would be required to provide FDA access to such records.

Proposed § 1.1124(a) provides that, in addition to meeting the records requirements of ISO/IEC 17011:2017 (as required by proposed § 1.1118(b)), an accreditation body that has been recognized must electronically maintain records demonstrating its compliance with the program, created while it is recognized, for 5 years after the date of creation of the record. The requirements of § 1.1124 would apply to accreditation bodies that have been recognized even if they later are no longer recognized. We are proposing this requirement because maintenance of such records could be vital to our management of this program.

We are not proposing to require records subject to this proposed section to be maintained in English. In accordance with our position on this issue in the accredited third-party certification final rule, we are proposing to allow recognized accreditation bodies to maintain and submit records in languages other than English, provided that they electronically submit an English translation within a reasonable time thereafter. We decline to set a specific timeframe for submission of the translation because the circumstances surrounding each request will differ (*e.g.,* varying number of documents/pages). Further, we are proposing under § 1.1124(b) to require that if FDA requests records electronically, the records must be submitted no later than 10 business days after the date of the request, with the exception that records covered by the immediate notification provision in § 1.1123(c) would be required to be submitted within 48 hours. By allowing records to be submitted in a language other than English, we think that it will not be unduly burdensome for recognized accreditation bodies to provide most requested records electronically within 10 days.

We have tentatively concluded that the records maintenance and access requirements in proposed § 1.1124 are necessary for us to adequately monitor recognized accreditation bodies, as we are directed to do by section 422(a)(7) of the FD&C Act. For example, access to such records could facilitate our determination of whether revocation of the accreditation body's recognition is warranted.

Proposed § 1.1124(c) further clarifies that recognized accreditation bodies must not prevent or interfere with FDA's access to the records accredited laboratories it accredits are required to maintain under proposed § 1.1153. When FDA requests, under proposed § 1.1153 or proposed § 1.1159, that a laboratory submit or provide FDA access to records the laboratory would be required to maintain under proposed § 1.1146(b) or proposed § 1.1153, we expect that the recognized accreditation body that accredits the laboratory would not interfere with our access to such records. Maintaining freedom of access to such records is important to facilitate FDA's ability to provide general oversight of the food testing program, with respect to both recognized accreditation bodies and accredited laboratories.

8. What internal audit requirements must a recognized accreditation body meet? (Proposed § 1.1125)

Proposed § 1.1125 would require a recognized accreditation body to audit its compliance with the requirements under § 1.1118(c) and (d) as part of the internal audit that a recognized accreditation body conducts under § 1.1118(b). Requiring recognized accreditation bodies to monitor their conformance to the requirements that are specific to this program, as well as to the requirements of ISO/IEC 17011:2017, would ensure that accreditation bodies' internal audits cover all the requirements of this program. As discussed, proposed § 1.1123(b)(1) would require the results of this audit to be submitted to us.

E. Proposed Provisions About Procedures for Recognition of Accreditation Bodies (Proposed §§ 1.1128 Through 1.1133)

In these sections we propose how an accreditation body may apply for recognition under this rule, propose procedures for recognition, probation, revocation, and relinquishment of recognition of accreditation bodies, and propose how FDA would oversee recognized accreditation bodies.

1. How does an accreditation body apply to FDA for recognition or renewal of recognition? (Proposed § 1.1128)

This proposed rule would establish procedures for accreditation bodies to follow when applying to FDA for recognition or renewal of recognition. Proposed § 1.1128(a) would provide that an accreditation body seeking recognition must submit an application to FDA demonstrating that it meets the eligibility requirements of proposed § 1.1113, which describes the proposed requirements for accreditation bodies to become recognized to accredit laboratories to conduct food testing under this program.

Similarly, proposed § 1.1128(b) would require an accreditation body seeking renewal of its recognition to submit a renewal application to us demonstrating that it continues to meet the requirements of this program.

Proposed § 1.1128(c) clarifies that accreditation bodies applying for recognition or renewal of recognition must submit documentation of conformance with ISO/IEC 17011:2017, and documentation of ILAC MRA signatory status demonstrating competence to ISO/IEC 17011:2017, in meeting the requirements of proposed § 1.1113(a) and (b) or proposed § 1.1118(a) and (b), as applicable. Although we recognize that documentation of ILAC MRA signatory status under this program represents a determination that an accreditation body has demonstrated competence to ISO/IEC 17011:2017, proposed § 1.1128(c) would require independent documentation that an accreditation body demonstrates competence to ISO/IEC 17011:2017 to provide us additional assurance that an accreditation body meets the specific requirements of the standard. Independent documentation of ISO/IEC 17011:2017 competence could include the report of a peer evaluation by a regional cooperation group or ILAC conducted as part of the

ILAC MRA application and evaluation process. An accreditation body applying for recognition or renewal of recognition also would be required to submit documentation demonstrating it meets the requirements for accreditation bodies that are specific to this program under proposed § 1.1113(c) and (d) or proposed § 1.1118(c) and (d), as applicable. We would expect documentation of proposed § 1.1113(c) and (d) to come in the form of documents such as standard operating procedures, records procedures, the resumes of the scientific and technical staff or contractors who review validation and verification studies, and examples of contracts the accreditation body uses in its activities, while documentation of proposed § 1.1118(c) and (d) would consist of documents created during the accreditation body's term of recognition, such as the internal audit required under proposed § 1.1125. We request comments on what additional documents would demonstrate that an accreditation body meets the requirements of proposed § 1.1113(c) and (d) and proposed § 1.1118(c) and (d).

Where the application for recognition or renewal of recognition does not sufficiently demonstrate that the accreditation body meets the requirements for recognition by FDA, it may be necessary for FDA to review additional documentation to determine whether the accreditation body meets the recognition requirements of the program, and FDA also may, as is noted by proposed § 1.1129(b), request and conduct an onsite assessment of the applicant if necessary. Such additional documentation may include the accreditation body's reviews, assessments, and investigations of laboratories; results of the accreditation body's self-monitoring and internal audits; documents and other information regarding the accreditation body's authority, qualifications (including the expertise and training of its employees that assess laboratories that conduct food testing), resources, quality assurance program, and recordkeeping, reporting, notification, and monitoring procedures. For applications for renewal of recognition, FDA may also review documents and other information of one or more of the laboratories that are accredited by the recognized accreditation body.

Applications for recognition and renewal are subject to certain requirements for the form and manner of submission. Under paragraphs (d) and (e) of proposed § 1.1128 the accreditation body must submit to FDA a signed application (signed by the applicant or by an individual authorized to act on behalf of the applicant for purposes of seeking recognition or renewal of recognition), accompanied by any supporting documents, electronically and in English. We also propose to require an applicant to provide any translation or interpretation services we need to process the application. This may include providing translators or interpreters for FDA staff conducting onsite assessments of the applicant. We invite comment on our proposal to require submissions in English and to require translation or interpretation services as necessary.

2. How will FDA review applications for recognition and applications for renewal of recognition? (Proposed § 1.1129)

Under proposed § 1.1129(a), FDA would review an accreditation body's recognition or renewal application for completeness and would notify the applicant of any deficiencies. We are proposing to review applications on a first-in, first-out basis according to the date the accreditation body submits the completed application. However, we may prioritize the review of specific applications based on program needs. To encourage applicants to supply any missing information promptly, we will not place an application in the queue for review until it is complete. Allowing incomplete applications in the queue might hold up applications that are ready for review, but were submitted later in time.

Under proposed § 1.1129(b), FDA would evaluate applications to determine whether the applicant meets the requirements for recognition or renewal of recognition. The evaluation may include an onsite assessment of the accreditation body. For renewal applications, if FDA does not reach a final decision before an accreditation body's recognition terminates by expiration, FDA may extend the terms of recognition for a specified period of time or until FDA reaches a final decision on the renewal application. Proposed § 1.1129(b) further provides that FDA would notify the applicant, in writing, regarding whether the application has been approved or denied, and that we may make such notification electronically.

Under proposed § 1.1129(c), we would notify applicants of our decision to approve the application for recognition or renewal through issuance of recognition that would list any conditions associated with the recognition, including the duration of recognition.

Proposed § 1.1129(d) would allow us to grant recognition to an accreditation body for up to 5 years at a time (except if FDA needs to extend the term of recognition while it makes a renewal determination, as described at proposed § 1.1129(b)), although we will determine the length of recognition on a case-by-case basis. We are proposing the 5-year upper limit in accordance with section 422(a)(7) of the FD&C Act, which requires us to (in pertinent part), periodically, and in no case less than once every 5 years, reevaluate accreditation bodies recognized under this program to assess whether they meet the criteria for recognition. We do not necessarily expect to grant every recognition at the maximum 5-year duration. We believe that shorter terms of recognition may potentially be appropriate in the initial years of the food testing program or for any accreditation bodies with fewer years of experience accrediting laboratories to conduct food testing. When we proposed the same duration for recognition of accreditation bodies for the accredited third-party certification regulation, we received support for the proposal and for the flexibility to determine the length of recognition on a case-by-case basis, although we also did receive some comments expressing concern that we did not propose a fixed duration of recognition (80 FR 74570 at 74601). As we noted in the accredited third-party certification final rule, where appropriate, we would grant recognition for the maximum duration of 5 years. Id. However, we also recognize it may be appropriate for the duration of recognition to vary depending on a number of factors, such as accreditation body experience and, for example, whether the accreditation body has had problems meeting the recognition requirements in the past.

Under proposed § 1.1129(e), if we deny a recognition or renewal application, we would notify the applicant, through an issuance of a notification of denial of recognition or denial of renewal application, that the accreditation body's recognition or renewal application has been denied. The notification of denial of recognition or denial of renewal application would state the basis for the denial and describe the procedures for requesting reconsideration of the application under § 1.1171.

Proposed § 1.1129(f) provides that an applicant whose application for renewal or recognition was denied by FDA must notify FDA electronically, in English, within 10 business days of the date of issuance of a denial of a renewal application, of the name and contact information of the custodian who will maintain the records it is required to

maintain under proposed § 1.1124(a) and to make them available to FDA as required by proposed § 1.1124(b). Proposed § 1.1129(f) would also require that the contact information for the custodian must include, at a minimum, an email address and the street address where the records required by proposed § 1.1124 will be located. As noted previously, under proposed § 1.1124 accreditation bodies that have been recognized must electronically maintain, for at least 5 years after the date of creation of the records, records subject to proposed § 1.1124 that were created during the term of recognition.

Under proposed § 1.1129(g), FDA would promptly issue a notice of the denial of the application for renewal of recognition of the accreditation body to all laboratories accredited by the accreditation body whose application for renewal of recognition was denied.

Under proposed § 1.1129(h), FDA would provide public notice on the website described in proposed § 1.1109 of the issuance of a denial of a renewal application and include the date of the issuance of the denial of a renewal application. This is the same approach we took in the accredited third-party certification regulation with respect to denials of renewal applications. See 21 CFR 1.631(h). We believe notification of denial of renewal would be important information to make easily available to interested parties and the public.

3. How will FDA oversee recognized accreditation bodies? (Proposed § 1.1130)

As noted above, section 422(a)(7)(A) of the FD&C Act requires us to periodically, and in no case less than once every 5 years, reevaluate recognized accreditation bodies. Section 422(a)(7)(B) of the FD&C Act requires us to promptly revoke the recognition of a recognized accreditation body for failure to meet the requirements of section 422 of the FD&C Act.

As we discuss above, proposed § 1.1129(d) provides that we may grant recognition of an accreditation body for a period not to exceed 5 years from the date of recognition. Proposed § 1.1130(a) provides that we will assess each recognized accreditation body to determine its compliance with the applicable requirements of this proposed rule by no later than 4 years after the date of recognition for a 5-year recognition period, or by no later than the midterm point for a recognition period of less than 5 years. Accordingly, we propose to assess recognized accreditation bodies at least once during their period of recognition, in addition to any assessment we may have conducted during our review of an application for recognition and in addition to any assessment we may conduct during a review of an application for renewal of recognition. Proposed § 1.1130(a) provides that our assessment of a recognized accreditation body may include review of records, an onsite assessment of the accreditation body, and onsite assessments of accredited laboratories the recognized accreditation body accredits, with or without the recognized accreditation body present (we would conduct such onsite assessments under proposed § 1.1159).

Proposed § 1.1130(b) provides that we may conduct additional assessments of a recognized accreditation body, at any time, to determine the recognized accreditation body's compliance with the applicable requirements of the program. We may or may not notify the recognized accreditation body that we will be conducting such an assessment, which may be onsite.

Our assessments of recognized accreditation bodies under proposed § 1.1130 may be as brief or as extensive as is warranted and may include our review of an accreditation body's accreditations, assessments, and investigations of laboratories; results of an accreditation body's internal audits; documents and other information accreditation bodies are required maintain under §§ 1.1118 and 1.1124 regarding the accreditation body's authority, qualifications, resources, quality assurance program, and recordkeeping, reporting, notification, and monitoring procedures.

4. When will FDA revoke the recognition of an accreditation body or put a recognized accreditation body on probation? (Proposed § 1.1131)

This proposed rule would establish the criteria and procedures for revocation of recognition of an accreditation body. Section 422(a)(7)(B) of the FD&C Act requires us to promptly revoke the recognition of any accreditation body found not to be in compliance with the requirements of section 422 of the FD&C Act. Accordingly, if a recognized accreditation body ceases to meet the criteria for recognition we establish under section 422 of the FD&C Act, we must revoke the recognized accreditation body's recognition.

Under proposed § 1.1131(a), we would revoke the recognition of an accreditation body if it fails to meet the requirements of this program, or where FDA determines the accreditation body has committed fraud or submitted material false statements to FDA.

Examples of what would qualify as a failure by a recognized accreditation body to meet the requirements of this program would include:

- Refusing to allow FDA to access records as required by proposed § 1.1124, to allow FDA to conduct an onsite assessment under proposed § 1.1130, or to allow FDA to otherwise conduct an assessment under proposed § 1.1130. Denial of access and ability to perform our oversight functions would prevent us from meeting our statutory responsibilities under section 422 of the FD&C Act to periodically reevaluate accreditation bodies and to promptly revoke the recognition of an accreditation body found not to be in compliance with section 422 of the FD&C Act.
- Demonstrating bias or lack of objectivity when conducting activities under this rule would violate the impartiality requirements of ISO/IEC 17011:2017, which recognized accreditation bodies must meet in accordance with § 1.1118(b).
- Failing to take timely and appropriate corrective action in accordance with ISO/IEC 17011:2017 (Ref. 12) section 9.5 (which proposed § 1.1118(b) of this rule would require the recognized accreditation body to comply with) after the recognized accreditation body identifies, or should have identified, that the recognized accreditation body is not operating in conformance with one or more requirements of this proposed rule.

Fraud or the submission of material false statements by recognized accreditation bodies would undermine our ability to implement the program and would undermine the program's integrity and credibility. We request comment on whether this section should also allow for FDA to revoke a recognized accreditation body's recognition for ''other good cause.'' If you submit a comment in favor of adding such a provision, we request the comment provide one or more examples of what would constitute such other good cause (and yet would not otherwise support revocation under the proposed § 1.1131(a)).

Proposed § 1.1131(b)(1) provides that, when we revoke an accreditation body's recognition we would notify the accreditation body that its recognition has been revoked through the issuance of a revocation stating the grounds for revocation, the procedures for requesting a regulatory hearing on the revocation under proposed § 1.1173, and the procedures for requesting reinstatement of recognition under proposed § 1.1133.

Proposed § 1.1131(b)(2) would require the accreditation body to, within 10 business days of the date of issuance of revocation, notify us electronically, in English, of the name of the custodian who will maintain records and make them available to FDA as required by proposed § 1.1124. Proposed § 1.1131(b)(2) further provides that the contact information for the custodian must include, at a minimum, an email address and the street address where the records will be located. As we have discussed previously, the accreditation body's responsibility under this proposed rule to maintain certain records created while it was recognized does not end when the accreditation body is no longer recognized.

Proposed § 1.1131(c) provides that if we determine that a recognized accreditation body has demonstrated deficiencies in performing its functions under this proposed rule that are less serious and more limited than those identified in proposed § 1.1131(a), and it is reasonably likely that the accreditation body will be able to correct such deficiencies within a reasonable period of time, we may temporarily put the recognized accreditation body on probation, rather than revoke its recognition, and request that the accreditation body take appropriate corrective actions. We expect that the probationary status of a recognized accreditation body would allow us to work with the recognized accreditation body to bring it into compliance with the requirements of the program without having to resort to the more permanent remedy of revoking recognition.

Proposed § 1.1131(d) provides that the probationary status of the recognized accreditation body would remain in effect until the recognized accreditation body demonstrates to our satisfaction that it has successfully addressed the deficiencies specified by FDA within the time period identified by FDA. Proposed § 1.1131(d) also provides that, alternatively, the probationary period would end if we determine that revocation of recognition is warranted. We would likely determine that revocation of recognition is appropriate if the accreditation body fails or refuses to take appropriate corrective actions, or otherwise does not comply with the conditions specified by the notification of probation within the timeframe specified, or if appropriate, an otherwise reasonable timeframe.

Proposed § 1.1131(e) provides that if we put the recognized accreditation body on probation, we would formally notify the accreditation body of its probation. The notification would describe the grounds for the probation, identify all deficiencies that must be corrected for us to lift the probation, would identify a specified period of time to take certain corrective actions to address the deficiencies specified by us.

Proposed § 1.1131(f) would provide that an accreditation body that has had its recognition revoked may not accredit laboratories under this program or continue to oversee the laboratories it has previously accredited. This provision would also clarify that a recognized accreditation body that has been put on probation by FDA is expected to continue to oversee laboratories that it has accredited under this subpart and is permitted to continue to accredit laboratories under § 1.1120 of this subpart. We would normally anticipate that such an accreditation body would continue to fulfill its responsibilities under this program during the probationary period. Note that FDA may conduct additional oversight of recognized accreditation bodies that are on probation, to help ensure quality and competency on the part of that particular accreditation body (and by extension for the integrity of the overall program).

Proposed § 1.1131(g) provides that FDA would issue a notice of the probation or revocation of recognition to all laboratories accredited by the accreditation body whose recognition was revoked or who was put on probation. In proposed § 1.1164, we address the effects on accredited laboratories of the revocation of the recognition of their accreditation bodies.

Proposed § 1.1131(h) clarifies that we would also provide notice on the website described in proposed § 1.1109, in accordance with proposed § 1.1109, of our issuance of probation or revocation of recognition of the accreditation body. This is consistent with the provisions of proposed § 1.1109.

We solicit comments on our tentative conclusions regarding possible grounds for probation and revocation of recognition, and with respect to the procedures and requirements we have proposed here related to revocation and probation of recognition.

5. What must a recognized accreditation body do if it wants to voluntarily relinquish its recognition or does not want to renew its recognition? (Proposed § 1.1132)

Proposed § 1.1132 requires a recognized accreditation body that voluntarily relinquishes its recognition before the recognition period terminates by expiration to follow certain procedures. Relinquishment on the initiative of the accreditation body is distinct from revocation of recognition under proposed § 1.1131 and is a mechanism provided to recognition bodies in the accredited third-party certification regulation and under FDA's mammography program. See 21 CFR 1.635 and 21 CFR 900.3(e). We are proposing certain procedural requirements, similar to those in the mammography and third-party accreditation programs, which accreditation bodies would be required to follow in relinquishing recognition or when a recognized accreditation body intends to allow its recognition to expire without seeking renewal. We believe these procedures are necessary to ensure an orderly transition for laboratories accredited by an accreditation body that is relinquishing its recognition or allowing it to expire and for us to make necessary adjustments in the program based on that relinquishment or expiration.

Proposed § 1.1132(a) describes the procedures that a recognized accreditation body would need to follow when it intends to relinquish its recognition or when it wishes to allow its recognition to expire without seeking renewal. In order to voluntarily relinquish its recognition or allow it to expire, a recognized accreditation body would need to notify FDA electronically and in English at least 60 days before voluntarily relinquishing its recognition or allowing its recognition to expire.

Proposed § 1.1132(a) would also require the recognized accreditation body to provide the name and contact information of the custodian who will maintain the records required under proposed § 1.1124 after the date of relinquishment or the date its recognition expires, as applicable, and make such records available to FDA as required by proposed § 1.1124. The contact information for the custodian must include, at a minimum, an email address and the street address where the records required by proposed § 1.1124 will be located.

Under proposed § 1.1132(b), we would require the accreditation body to notify the laboratories it had accredited that the accreditation body intends to relinquish its recognition or to allow its recognition to expire, specifying the date on which relinquishment or expiration will occur, and at least 60 days in advance.

Proposed § 1.1132(c) states that we would provide notice on the website described in proposed § 1.1109 of the voluntary relinquishment or expiration of recognition of an accreditation body. This provision is consistent with the provisions of proposed § 1.1109, which

would establish what information we would display on the website described by § 1.1109.

6. How does an accreditation body request reinstatement of recognition? (Proposed § 1.1133)

This proposed section describes the procedures that an accreditation body would have to follow when seeking reinstatement of its recognition. The procedures the accreditation body would be required to follow would differ depending on whether we revoked the accreditation body's recognition or the accreditation body voluntarily relinquished its recognition or allowed its recognition to expire.

Under proposed § 1.1133(a), an accreditation body that has had its recognition revoked may seek reinstatement of recognition by submitting a new application for recognition under proposed § 1.1128. The accreditation body must also submit evidence to us that the grounds for revocation have been resolved, including evidence addressing the cause(s) or condition(s) that were the basis for revocation, and it must identify measures it implemented to help ensure that such cause(s) or condition(s) are unlikely to recur.

Under proposed § 1.1133(b), an accreditation body that previously relinquished its recognition or allowed its recognition to expire may seek recognition by submitting a new application for recognition under proposed § 1.1128.

F. Proposed Provisions About Accreditation of Laboratories (Proposed § 1.1138)

This proposed rule would establish the requirements for a laboratory seeking accreditation by a recognized accreditation body to test food in this program. Section 422(a)(2) and (a)(5) of the FD&C Act mention independent private laboratories, laboratories run and operated by Federal agencies, States, localities, and foreign laboratories, as examples of laboratories that recognized accreditation bodies may accredit under this program, so long as they meet accreditation requirements for our program. We expect a variety of these types of laboratories would apply to this program. With regard to States in particular, it is our understanding that State and public university laboratories currently conduct a significant portion of the shell egg testing which would be covered by this proposed rule. We therefore believe some state laboratories would apply.

Section 422 of the FD&C Act contains requirements for laboratories to be accredited, including that they have a demonstrated capability to conduct one or more sampling and analytical testing methodologies for food (section 422(a)(2)) and that they meet model laboratory standards that FDA is required to develop (section 422(a)(6)).

Section 422(a)(6) of the FD&C Act further requires that the model laboratory standards include methods to ensure that: (1) Appropriate analytical procedures (including rapid analytical procedures), and commercially available techniques are followed and reports of analyses are certified as true and accurate (section 422(a)(6)(A)(i)); (2) internal quality systems are established and maintained (section 422(a)(6)(A)(ii)); (3) procedures exist to evaluate and respond promptly to complaints regarding analyses and other activities for which the laboratory is accredited (section 422(a)(6)(A)(iii)); and (4) individuals who conduct the analyses are qualified by training and experience to do so (section 422(a)(6)(A)(iv)). Section 422(a)(6)(B) of the FD&C Act also authorizes us to include in the model laboratory standards any other criteria we determine are appropriate.

Section 422(a)(6) of the FD&C Act directs us to consult existing standards for guidance in developing the model laboratory standards for use in qualifying laboratories for accreditation. As discussed, we have consulted, and propose to incorporate by reference, ISO/IEC 17025:2017. The model laboratory standards we are proposing consist of ISO/IEC 17025:2017, which laboratories would be required to meet (except for a few provisions, as we discuss in more detail below) to become accredited in accordance with proposed § 1.1138(a)(2), and our additional proposed requirements in §§ 1.1146 through 1.1158. For example, ISO/IEC 17025:2017 (Ref. 13) section 7.9 requires accredited laboratories to establish a process for evaluating and responding to complaints, which we tentatively conclude would fulfill the model laboratory standard requirement of section 422(a)(6)(A)(iii) of the FD&C Act.

We carefully considered whether to include a sampling accreditation requirement in the proposed rule. Proper sampling procedures are essential in order for analytical testing results to convey meaningful information about the food product or environment at issue. Accreditation for sampling could increase confidence in the training and procedures of samplers and potentially help ensure the collection of representative samples.

According to our analysis (Ref. 1) of the applicable data stored in our internal systems, from January 1, 2016, to December 31, 2017, approximately 63 percent of sampling conducted for analysis in support of admission of food offered for import that we had detained without physical examination was conducted by five entities accredited for sampling under ISO/IEC 17025. Approximately 37 percent of such sampling conducted during that time was conducted by more than 300 entities not accredited for sampling under any standard.

It is our understanding that whereas under the 2005 version of ISO/IEC 17025 only laboratories are eligible for accreditation, starting with the 2017 version of ISO/IEC 17025, entities that do not conduct any analyses (*i.e.,* an entity that solely collects samples) may be considered for accreditation for sampling under ISO/IEC 17025. It is also our understanding that it will take some time to develop and implement this new policy. Some of the larger laboratory accreditation bodies in the United States indicated that demand for accrediting entities that only conduct sampling is still relatively small, and thus far, these accreditation bodies have not performed accreditation assessments of such entities. (See Meeting Minutes, ''Sampling Accreditation Discussion with A[ccreditation] B[odie]s,'' November 13, 2017 (Ref. 14).) As the ISO/IEC 17025 revision is still relatively new, FDA is not able to adequately assess the accreditation of entities that only conduct sampling at this time.

Given these considerations, we are not proposing requirements for the accreditation of sampling in this proposed rule. However, we strongly encourage all samplers to consider accreditation, and we may reassess our position after accreditation bodies have gained experience with accrediting entities that only conduct sampling. We will watch developments in this area with interest, and would be willing to consider expanding the proposed program to include accreditation of laboratories and sampling services to perform sampling in the future.

While we are not proposing requirements for accreditation of samplers, we invite comment on the matter. More specifically, what is the current capacity of accredited sampling entities, both laboratories and sampling services (*i.e.,* entities that only perform sampling)? Are there attributes unique to sampling that present challenges in terms of the continued development of this field? What existing standards (*e.g.,*

ISO/IEC 17025, ISO 9001, ISO/IEC 17020) would be best to use as a basis for developing a more comprehensive and focused consensus sampling standard? What are the critical detailed requirements that should be included in a consensus sampling standard to ensure food safety? What standards are currently employed to assess samplers, are they effective, and in what ways are they insufficient?

We note that because we are not proposing accreditation for sampling under this proposed rule, we would not expect laboratories seeking to become accredited under this program to demonstrate the capability to conduct sampling methods under this program if finalized. If we were to propose to require accreditation for sampling under the authority of section 422 of the FD&C Act in the future, at that time we would likely propose that entities seeking to become accredited for sampling would have to demonstrate the capability to conduct one or more methods of sampling for food testing.

What requirements must a laboratory meet to become accredited by a recognized accreditation body? (Proposed § 1.1138)

Proposed § 1.1138 states the requirements a laboratory must meet to be accredited by a recognized accreditation body to conduct food testing under this program.

Section 422(a)(2) of the FD&C Act requires, in pertinent part, that this program provide for the accreditation of laboratories with a demonstrated capability to conduct one or more analytical testing methodologies for food and section 422(b)(1) of the FD&C Act requires, in pertinent part, that food testing under this program be conducted by laboratories that have been accredited for the appropriate analytical testing methodology. We have considered these two provisions and propose to interpret section 422(b)(1) as requiring laboratories to be accredited on a method-specific basis, and to interpret section 422(a)(2) of the FD&C Act to mean that a laboratory may become accredited even if it seeks to be accredited for a single method. Accordingly, proposed § 1.1138(a)(1) would require that a laboratory seeking to be accredited must demonstrate that it is capable of conducting each method of food testing for which it seeks to be accredited. The laboratory would have to do so by meeting the requirements described under proposed § 1.1138(a)(1)(i) and (ii).

Proposed § 1.1138(a)(1)(i) and (ii) clarify how an accredited laboratory must demonstrate it is capable of conducting each method for which it seeks to be accredited. Proposed § 1.1138(a)(1)(i) provides that a laboratory must do so by submitting information related to validation or verification studies.

Validation studies are required in certain circumstances by ISO/IEC 17025:2017 (Ref. 13) section 7.2, which we have already incorporated by reference, but which we would explicitly require in proposed § 1.1151(c)(1). For example, a validation study would be required when a laboratory seeks to be accredited for a non-standard method or for a standard method it will use outside the method's intended application. Validation is meant to demonstrate that a method is suitable for the intended purpose.

Method verification is meant to verify that the laboratory can properly apply the method for a specific intended use, specifically with respect to the limit of detection or probability of detection. We would require verification studies in proposed § 1.1151(d)(1), and proposed § 1.1151(d)(2) would require an accredited laboratory to record certain information related to a verification study (*e.g.,* the results of the verification, supporting analytical data) (we discuss proposed § 1.1151(d)(1) and (2) in more detail in section VI.G.7). Under this program, a laboratory may demonstrate that it is capable of conducting a particular method by submitting to the recognized accreditation body the verification study information required in proposed § 1.1151(d)(2).

To be clear, under this program a laboratory may fulfill the requirements of proposed § 1.1138(a)(1)(i) by submitting to the recognized accreditation body either validation study information or verification study information.

Proposed § 1.1138(a)(1)(ii) provides that the laboratory must also, in order to demonstrate it is capable of conducting a method of food testing for which it seeks to be accredited, pass, or have passed within the past year, a proficiency test for the method(s), subject to the exception that if the laboratory determines there is no proficiency testing program available that addresses the method, or that proficiency testing for the method is otherwise impracticable, the accredited laboratory may instead subject, or have subjected in the past year, the method to an appropriate comparison program. This proposed requirement and exception reflect a similar requirement and exception in AOAC International's Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals, An Aid to Interpretation of ISO/IEC 17025:2005 (April 2015 revision) (AOAC 17025 Guidelines) (Ref. 9) at section 5.9.1. Proposed § 1.1138(a)(1)(ii) further provides that the laboratory's determination there is no proficiency testing program available that addresses the method must be reviewed, and approved or denied (as appropriate), by the recognized accreditation body from which the laboratory is seeking accreditation. For more information about the exception in proposed § 1.1138(a)(1)(ii), please see our discussion of proposed § 1.1148(a)(2) below at section VI.G.3.

Under proposed § 1.1138(a)(2) a laboratory seeking accreditation under this program must demonstrate it meets (or, with respect to activities the laboratory may only conduct once accredited, is capable of meeting) the requirements of ISO/IEC 17025:2017. ISO/IEC 17025:2017 sets general standards for the competence of testing laboratories, including general management requirements such as impartiality and quality assurance. There are, however, a few provisions in ISO/IEC 17025:2017 that we propose to exclude from our requirements, as reflected in proposed § 1.1138(b). Section 7.3 of ISO/IEC 17025:2017 (Ref. 13), which addresses sampling, would be excluded because, as discussed previously, we are not proposing accreditation of sampling (see the introduction to section VI.F for additional discussion of this issue). We also are not proposing to require laboratories to meet ISO/IEC 17025:2017 section 7.8, which describes requirements for reporting test results to customers, to avoid potential conflicts with proposed § 1.1152, which contains requirements for the food testing results and supporting documentation that are necessary for us to assess the validity of food testing conducted under this program. We are also proposing in § 1.1138(b) that laboratories seeking accreditation are not required to meet, or demonstrate that they are capable of meeting, requirements of ISO/IEC 17025:2017 that relate to the relationship between the laboratory and its customers, to the extent that such provisions establish obligations that conflict with the requirements of this rule. For example, ISO/IEC 17025:2017 section 7.1.1(d) would require the laboratory to ensure that the methods it uses are capable of meeting the customers' requirements, ISO/IEC 17025:2017 section 7.2.1.4 indicates that the laboratory's customer may choose

the method of analysis to be used for food testing, and ISO/IEC 17025:2017 section 7.2.1.7 would restrict the laboratory from deviating from a method if the customer does not accept the deviation. As such, requiring accredited laboratories to meet all of the customer requirement provisions of ISO/IEC 17025:2017 could create potential conflicts with the requirements of section 422 of the FD&C Act.

Proposed § 1.1138(c) would require laboratories seeking accreditation to demonstrate they are capable of meeting and operating in conformance with all of this subpart's requirements for accredited laboratories. For example, under proposed §§ 1.1152 and 1.1153 laboratories would have to meet certain requirements specific to this program relating to reporting, notifications, and records, and under proposed § 1.1148 laboratories would have to meet certain quality assurance requirements specific to this program and beyond the requirements in ISO/IEC 17025:2017. A laboratory would have to demonstrate that it has implemented written procedures to meet those requirements of this proposed rule so that it will be able to comply with such requirements once it is accredited.

G. Proposed Requirements for Accredited Laboratories (Proposed §§ 1.1146 Through 1.1153)

Proposed §§ 1.1146 through 1.1153 would establish certain model laboratory standards that accredited laboratories must meet to remain accredited. In accordance with section 422(a)(6)(A) of the FD&C Act, these model laboratory standards would help ensure that appropriate analytical procedures and commercially available techniques are followed and reports of analyses are certified as true and accurate; internal quality systems are established and maintained; procedures exist to evaluate and respond promptly to complaints regarding analyses for which the laboratory is accredited; and individuals who conduct analyses are qualified by training and experience to do so. In accordance with section 422(a)(6)(B) of the FD&C Act, we have also proposed additional requirements that laboratories would have to meet to remain accredited, such as certain requirements relating to methods of analysis, notifications and submissions to FDA, and recordkeeping.

1. What are the general requirements for accredited laboratories to remain accredited? (Proposed § 1.1146)

Proposed § 1.1146 provides that for an accredited laboratory to remain accredited, the accredited laboratory must be capable of conducting each method of analysis for the testing of food for which it is accredited, continue to conform to the applicable provisions of ISO/IEC 17025:2017, and fulfill the additional requirements of this subpart. For a discussion of why we believe these ISO/IEC 17205:2017 requirements are important for laboratories to meet to be accredited under this proposed rule, please see our previous discussion of proposed § 1.1138 in section VI.F.1.

2. What impartiality and conflict of interest requirements must accredited laboratories meet? (Proposed § 1.1147)

Proposed § 1.1147 would require accredited laboratories to meet certain requirements related to impartiality and conflicts of interest in addition to those impartiality and conflict of interest requirements of ISO/IEC 17025:2017 they would have to meet in accordance with proposed § 1.1146(b).

ISO/IEC 17025:2017 contains several requirements related to impartiality and conflicts of interest that accredited laboratories would have to meet under proposed § 1.1146(b). For example, ISO/IEC 17025:2017 (Ref. 13) section 4.1 requires the laboratory to conduct its activities impartially and to be structured and managed so as to safeguard impartiality, to not allow commercial, financial, or other pressures to compromise its impartiality, and that, if a risk to impartiality is identified, the laboratory must be able to demonstrate how the laboratory eliminates or minimizes the risk.

However, we have tentatively determined that additional requirements related to impartiality and conflicts of interest are appropriate in the context of this rule. With certain exceptions, proposed § 1.1147(a) would prohibit the accredited laboratory's officers, employees, contractors, and agents involved in food testing and related activities from accepting any money, gift, gratuity, or other item of value from the owner or consignee of the food that is being tested or will be tested by the accredited laboratory. Proposed § 1.1147(b)(1) and (2) provide the caveats that the prohibited items of value specified in proposed § 1.1147(a) do not include payment of fees for food testing services or reimbursement of direct costs associated with the food testing by the accredited laboratory. With respect to accredited laboratories that are owned by the owner or consignee of the food that is tested or to be tested, proposed § 1.1147(b)(3) provides that the prohibited items of value specified in proposed § 1.1147(a) also do not include the officer's, employee's, contractor's, or agent's compensation in the normal course of business.

Proposed § 1.1147(c) would require the owner or consignee's payment to the accredited laboratory for food testing services and/or reimbursement of direct costs associated with food testing to be independent of whether the test results indicate the tested food is or appears to be violative. It is crucial that the accredited laboratory be able to conduct its testing without fear of receiving reduced payment or no payment from the owner or consignee if the food testing results are violative. We seek comment with respect to whether there are more effective provisions that might achieve the aim of impartial food testing.

3. What quality assurance requirements must accredited laboratories meet? (Proposed § 1.1148)

Proposed § 1.1148 would establish quality assurance requirements accredited laboratories must meet for proficiency testing and the use of reference materials and quality control samples, in addition to the ISO/IEC 17025:2017 quality assurance requirements accredited laboratories would need to meet under proposed § 1.1146(b). Specifically, under proposed § 1.1146(b), accredited laboratories would have to develop, maintain, and implement a complaints program (see ISO/IEC 17025:2017 (Ref. 13) section 7.9), a program to control nonconforming testing work (see ISO/IEC 17025:2017 section 7.10), a program to continually improve (see ISO/IEC 17025:2017 section 8.6), a corrective action program (see ISO/IEC 17025:2017 section 8.7), an internal audit program (see ISO/IEC 17025:2017 section 8.8), a management review program (see ISO/IEC 17025:2017 section 8.9), and policies for ensuring the validity of test results (see ISO/IEC 17025:2017 section 7.7).

As described by ISO/IEC 17025:2017, proficiency testing evaluates laboratory performance against established criteria. ISO/IEC 17025:2017 (Ref. 13) section 7.7.2 provides that accredited laboratories must participate in proficiency testing and/or interlaboratory comparison programs other than proficiency testing. ISO/IEC 17011:2017 (which applies to accreditation bodies), indicates that the accreditation body's review of proficiency test results may help it assess laboratories, but ISO/IEC 17011:2017 does not require accreditation bodies to require the laboratories they accredit to participate in a proficiency testing program (ISO/

IEC 17011:2017 (Ref. 12) at section 3.24 n.1). Although both ISO/IEC standards address proficiency testing, we are proposing more specific proficiency testing requirements in this document to support the regular evaluation of the performance of accredited laboratories in this program.

Proposed § 1.1148(a)(1) would require accredited laboratories to participate in a proficiency testing program or programs, provided by a competent proficiency testing organization, and ensure that proficiency testing is conducted at least once per year for each method within the accredited laboratory's scope of accreditation (subject to an exception in proposed § 1.1148(a)(2), which we discuss below). In developing proposed § 1.1148(a), we considered how various existing standards address the frequency and coverage of laboratory proficiency testing. Some accreditation bodies that accredit food testing laboratories require laboratories they accredit to conduct proficiency testing on their entire scope of accreditation over a four-year accreditation period and participate in at least one proficiency testing activity per year. (See, *e.g.,* ''R103—General Requirements: Proficiency Testing for ISO/IEC Laboratories,'' American Association for Laboratory Accreditation (Ref. 15), at p. 6; and ''Accreditation Requirements: ISO/IEC 17025 Testing Laboratories (Non-Forensics),'' ANSI/ASQ National Accreditation Board (Ref. 16), at pp. 4–5). We note that if only one proficiency testing activity takes place each year, the bulk of proficiency testing for a laboratory's scope of accreditation could occur at one time during the laboratory's accreditation period. We tentatively conclude that requiring yearly proficiency testing for each method on a laboratory's scope of accreditation would encourage more periodic proficiency testing throughout the accreditation period. This element of proposed § 1.1148(a) is based on the AOAC 17025 Guidelines (Ref. 9) at section 5.9.1, which provides that laboratories participate in at least one proficiency test annually for each ''test, type of test/method, and/or technique on the scope of accreditation''. Periodic proficiency testing throughout the four-year accreditation period should also help the accredited laboratory manage its other ongoing quality assurance activities (*e.g.,* its control of nonconforming testing work under ISO/IEC 17025:2017 (Ref. 13) section 7.10 and its program to continually improve under ISO/IEC 17025:2017 section 8.6). We seek comments on our proposed requirements for the frequency of proficiency testing.

We are proposing to require in § 1.1148(a)(1) that the proficiency test provider be ''competent.'' We note that ISO/IEC 17043:2010, ''Conformity Assessment—General Requirements for Proficiency Testing'' (Ref. 17) provides specific standards for proficiency test providers. We are requesting comment on whether, and if so, under what circumstances, we should require accredited laboratories to only use proficiency test providers accredited to ISO/IEC 17043 for proficiency testing under this proposed rule.

Proposed § 1.1148(a)(2) describes an exception to the proposed proficiency testing requirement. Proposed § 1.1148(a)(2) states that if the accredited laboratory determines there is no proficiency testing program available that addresses a particular method of analysis in the accredited laboratory's scope of accreditation, or that participating in a proficiency testing program for the particular method is otherwise impracticable, the accredited laboratory may subject that method to an appropriate comparison program. The laboratory's determination must be reviewed, and approved or denied (as appropriate), by the recognized accreditation body that accredits the laboratory. The AOAC 17025 Guidelines (Ref. 9) at section 5.9.1 provide a helpful list of examples of such alternative comparison programs.

Proposed § 1.1148(b) would require accredited laboratories to ensure their procedures for monitoring the validity of the results of testing it conducts under this program include the use of reference materials or quality control samples with each batch of samples it tests under this program. This requirement reflects a similar requirement in the AOAC 17025 Guidelines (Ref. 9), at section 5.9.1. ISO/IEC 17025:2017 (Ref. 13) section 7.7, which accredited laboratories must comply with under proposed § 1.1146(b), requires that laboratories' procedures for monitoring the validity of their results ''include, where appropriate'' use of reference materials or quality control materials. We tentatively agree with the AOAC 17025 Guidelines that it is always appropriate to use of reference materials or quality control samples when conducting food testing. Therefore, to encourage clarity and consistency with respect to the use of reference materials and quality control samples under this program, we have proposed to adopt the AOAC 17025 Guidelines' position on this issue.

4. What oversight standards apply to sampling? (Proposed § 1.1149)

Because we are not proposing accreditation for sampling, we are not proposing model standards for sampling. However, whether a sample is collected and maintained properly is integral to whether analysis of that sample will produce information that is of regulatory significance. For example, if the analyzed sample(s) is not representative of the food product or environment at issue, the analysis of the sample(s) will not result in information that is meaningful with respect to the food product or environment at issue. Accordingly, we are proposing provisions that would allow us to exercise oversight over the sampling conducted as part of this program. Proposed § 1.1149 would require the accredited laboratory to develop or obtain (depending on whether the accredited laboratory or a different entity collected the sample) and submit to FDA certain information about the sampler and sampling before the accredited laboratory analyzes the collected sample.

Specifically, proposed § 1.1149(a) would require that, before the accredited laboratory analyzes the sample, it must either develop (if it collected the sample) or obtain (if another entity collected the sample) the following documentation:

- Written documentation of the sampler's applicable qualifications by training and experience. If the accredited laboratory collects the sample, the accredited laboratory would need to develop such documentation the first time the individual collects a sample under this subpart. If another entity collects the sample, the accredited laboratory would need to obtain such documentation the first time it receives a sample collected under this subpart from that sampler. The accredited laboratory must also develop or obtain such documentation if the accredited laboratory learns that the sampler's qualifications have significantly changed since the accredited laboratory last developed or obtained documentation of the sampler's qualifications.
- A written sampling plan used to conduct the sampling. The written sampling plan must identify the sampler and must list factors that will be controlled to ensure the sampling does not impact the validity of the subsequent analytical testing, including controlling for the representational nature of the sample. This information would help us determine whether the sampling conducted would result in a

sample that is representative of the food product or environment in question. Identification of the sampler would allow us to determine whether we have the sampler's qualifications on file already and/or whether their qualifications may now be significantly different.

- A written sample collection report for each sample collected. The written sample collection report must, at a minimum, include:
  - The product code of the food product sampled (if product is being sampled) or the location of and a description of the environment (if environment is being sampled). This information would help us determine whether the correct lot or lots were sampled and whether the sample is otherwise representative of the food product or environment in question.
  - The date(s) of the sampling. This information would help us, in part, identify whether certain lots were sampled and help us review the chain of custody of the sample. For example, if the sample was collected a significant amount of time before the analysis, we may evaluate whether the documented chain of custody procedures for the sample would have preserved the sample's integrity.
  - The size, identity, and quantity of the sample(s). This information would help us determine whether the sample is representative of the food product or environment in question.
  - Documentation of sample collection procedures and any sample preparation techniques. This information would help us determine whether the sampling resulted in a sample that is representative of the food product or environment at issue.
  - Documentation of the chain of custody of the sample(s), and of measures taken, to not impact the validity of the subsequent analytical testing, including controlling for the representational nature of the sample(s). This information would help us determine whether the sample received by the laboratory is the sample that was collected from the product or environment at issue and whether the integrity of the collected sample was compromised between collection of the sample and its analysis. Documentation of the chain of custody should account for the continuous custody of the sample and indicate any gaps in the chain of custody. Documentation of measures taken to not impact the validity of the subsequent analytical testing, including controlling for the representational nature of the sample(s), might include, for example, documentation of the use of tamper-evident containers, use of secure storage spaces, and any refrigeration or freezing of the sample. The documentation should indicate at what point in the chain of custody such measures were taken.

Proposed § 1.1149(b) clarifies that we may consider the analysis of a sample to be invalid if the requirements of § 1.1149(a) are not met.

5. What requirements apply to analysis of samples by an accredited laboratory? (Proposed § 1.1150)

Proposed § 1.1150 would establish standards that laboratory analysis conducted under this proposed rule would need to meet, procedures the analysis would need to follow, and other requirements such as the qualifications of the individuals who perform the analysis. Proposed § 1.1150 explicitly states that accredited laboratories must meet the requirements of this section in addition meeting to the requirements in ISO/IEC 17025:2017 relating to analysis that an accredited laboratory is required to meet under § 1.1146(b).

Proposed § 1.1150(a) would require the analysis to be conducted on either the sample(s) received, or, if appropriate for the analysis, on a representative sample of the sample(s) received. Because the sample(s) received may consist of too much material to analyze in its entirety, a laboratory will often take a subsample(s) from the sample(s) received. The laboratory must ensure that it follows appropriate procedures so that the subsample(s) they analyze are representative of the lot. For example, in some circumstances it may be appropriate to homogenize the sample(s) by grinding, sieving, blending, or mixing the original sample(s) and taking a subsample(s) from the resulting mixture.

Proposed § 1.1150(b) would require that the analyst(s) that conducts the analysis be qualified by appropriate education, training, and/or experience to conduct the analysis; to have appropriately demonstrated their ability to conduct the method properly in the specific context of the food testing to be conducted; and to be in compliance with the conflict of interest requirements of proposed § 1.1146(b) (*i.e.,* the applicable sections of ISO/IEC 17025:2017) and proposed § 1.1147. Of note, under proposed § 1.1152(g)(12) (which we discuss in more detail at section VI.G.8), the laboratory must provide certain information about the analyst's or analysts' qualifications to us at our request.

Proposed § 1.1150(c) clarifies that the method used to conduct the food testing must meet the requirements of proposed § 1.1151 (requirements for methods of analysis, which we discuss at section VI.G.7).

Proposed § 1.1150(d) requires that the accredited laboratory document the testing information and test results to the extent necessary to account for all information that is required to be included in a full analytical report. Please see our discussion of proposed § 1.1152(g) for more information about what information full analytical reports must contain.

5. What requirements apply to the methods of analysis an accredited laboratory uses to conduct food testing under this subpart? (Proposed § 1.1151)

Food testing subject to section 422(b)(1) of the FD&C Act must be conducted by accredited laboratories that have been accredited for the appropriate analytical testing methodology or methodologies.'' Proposed § 1.1151 would establish certain requirements with regard to methods of analysis, which would apply in addition to the requirements in ISO/IEC 17025:2017 (Ref. 13) section 7.2 relating to selection, validation, and verification of methods (under proposed § 1.1146(b)).

Proposed § 1.1151(a) would require that analysis under this program be conducted using a method(s) of analysis that: (1) Is fit for purpose, (2) is within the accredited laboratory's scope of accreditation, (3) has been appropriately validated for use in such food testing, in accordance with § 1.1146(b) (*i.e.,* the applicable ISO/IEC 17025:2017 provisions) and paragraph (c) of § 1.1151, and (4) has been appropriately verified by the accredited laboratory for use in such food testing, in accordance with paragraph (d) of § 1.1151.

As we noted above, proposed § 1.1151(a)(1) would state that all methods of analysis used in food testing under this rule would have to be fit for purpose, in that they may only be applied for the food testing to which they are intended to apply and for the purpose for which they are validated. For example, if a method of analysis was developed and validated only for determining the presence and level of chloramphenicol in shrimp, the method may only be used to determine the presence and level of chloramphenicol in shrimp. The concept of fit for purpose is related to the concept of validation, in that successful validation of a method for a purpose for which the method had not yet been validated would typically demonstrate that the method is in fact fit for that purpose. For example, if the method that has

been validated only for determining the presence and level of chloramphenicol in shrimp is subsequently validated for determining the presence and level of chloramphenicol in fish, the method could then be applied as fit for the purpose of determining the presence and level of chloramphenicol in fish.

Proposed § 1.1151(a)(2) would require that the method used be included within the accredited laboratory's scope of accreditation. This requirement flows from section 422(a)(6) of the FD&C Act, which requires laboratories to be accredited for the specified testing methods they use for food testing in this program. Note that while some of the food testing that would be covered by this program is static (*e.g.,* the testing of shell eggs described in § 118.4(a)(2)(i)) other testing scenarios covered by this program are dynamic and will change with different circumstances (*e.g.,* testing to support removal from Import Alert). Therefore, we are not proposing a defined inventory of possible scopes; rather, under this program laboratories would be able to become accredited for a variety of food analytical methods, such as methods listed in the Bacteriological Analytical Manual (BAM) of procedures preferred by FDA for the detection of pathogens and microbial toxins in food (see *https://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm*).

Proposed § 1.1151(a)(3) and (4), respectively, would require that the method must have been appropriately validated for use in the food testing to be conducted and have been appropriately verified by the accredited laboratory for use in such food testing. We have issued procedures for our laboratories on these issues (*e.g.,* ''Methods, Method Verification and Validation,'' ORA Laboratory Manual Vol. II Section 2, document number 5.4.5 (Ref. 18) and ''Guidelines for the Validation of Chemical Methods for the FDA FVM Program, 2nd Edition'' (Ref. 19)), and we note that many food testing laboratories currently adhere to voluntary consensus standards and procedures issued by organizations, such as ISO and AOAC International, that address how to ensure analytical methods used by the laboratory are fit for purpose and appropriately validated and verified. Depending on the needs of the program as it develops, in the future we may issue guidance on this topic. Note that FDA maintains a website listing of all the FDA regulatory methods currently being used for food and feed safety programs, including links to other online manuals/compendia of methods (at *https://www.fda.gov/food/science-research-food/laboratory-methods-food*). On that web page we also provide links to the method development, validation, and implementation guidelines of FDA's Office of Food Policy and Response, and a list of methods currently undergoing validation.

Proposed § 1.1151(b) provides that with respect to food testing conducted under proposed § 1.1107(a)(1), the method or methods of analysis (if any) prescribed by the applicable testing requirement in the FD&C Act or implementing regulations are the only appropriate methods for the food testing to be conducted; and with respect to food testing conducted under proposed § 1.1107(a)(2), the method or methods of analysis (if any) prescribed by the food testing order are the only appropriate methods for the food testing to be conducted. In such cases, the statute, regulation, or food testing order would dictate the appropriate method for the food testing.

Proposed § 1151.1(c)(1) would make explicit for this program the validation requirement in ISO/IEC 17025:2017 (Ref. 13) section 7.2.2, which accredited laboratories must follow in accordance with proposed § 1.1146(b). As stated in ISO/IEC 17025:2017 section 7.2.2, accredited laboratories would be required to validate ''non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified.''

Proposed § 1.1151(c)(2) would require an accredited laboratory validating a method under this subpart to record all the information required by ISO/IEC 17025:2017 (Ref. 13) section 7.2.2.4 as well as the supporting analytical data. In the context of validation studies, supporting analytical data may include information about the detection limit, selectivity of method, linearity, limit of repeatability and/or reproducibility (accuracy and precision), robustness against external influences and/or cross sensitivity against interference from the matrix of sample. We have tentatively determined that this information is necessary for us to assess the validation and determine whether it demonstrates that the accredited laboratory can properly apply the method for the specific intended use.

Proposed § 1.1151(d)(1) provides that before an accredited laboratory conducts food testing under this program using a method for a specific intended use for which the method has been validated, but for which the laboratory has not previously applied the method under this program, the accredited laboratory must have verified it can properly perform the method for the specific intended use. We propose to make this requirement explicit for this program; and believe it is consistent with ISO/IEC 17025:2017 (Ref. 13) section 7.2.1 (which accredited laboratories must follow in accordance with proposed § 1.1146(b)), which requires that accredited laboratories verify a method before they introduce the method.

Proposed § 1.1151(d)(2) would require that an accredited laboratory performing verification of a method under this subpart must record: The method that is the subject of the verification, the intended purpose of the analysis, the results of the verification, the procedure used for the verification, supporting analytical data, and whether the accredited laboratory is able to properly perform the method. We have tentatively determined that this information is necessary for us to determine whether the verification is valid.

Section 422(b)(3) of the FD&C Act provides that FDA may waive requirements of section 422(b) if a new methodology or methodologies have been developed and validated but a laboratory has not yet been accredited to perform such methodology or methodologies; and the use of such methodology or methodologies are necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak. In accordance with this statutory provision, proposed § 1.1151(e) provides that an accredited laboratory may submit a written request to FDA requesting FDA's permission to use a method or methods outside of its scope of accreditation for food testing. FDA may approve the request if both of the following conditions are satisfied: (1) A new methodology or methodologies have been developed and validated but no reasonably available laboratory has been accredited to perform such methodology or methodologies and (2) the use of such method or methods is necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak. We propose to interpret section 422(b)(3)(A) of the FD&C Act to allow waiver of section 422(b)'s requirements when no ''reasonably available'' laboratory has been accredited to perform such a methodology. If an accredited laboratory exists but is not reasonably available (*e.g.,* due to geographic location, capacity constraints, or other factors), such a laboratory would not be able to address the emergent circumstances in which section 422(b)(3) applies. Therefore, if no ''reasonably available'' laboratory has been accredited to

perform the methodology in question, we believe section 422(b)(3)(A) of the FD&C Act may be interpreted to permit waiver of section 422(b)'s requirements. We have tentatively determined that any laboratory that conducts food testing under the exception of section 422(b)(3) of the FD&C Act must be accredited for at least one method under this program, because such accreditation would ensure that all of the requirements for this program apply to the laboratory and would ensure an important level of general competence and reliability.

7. What notifications, results, and reports must accredited laboratories submit to FDA? (Proposed § 1.1152)

Proposed § 1.1152 would require that accredited laboratories submit test results, sampling reports, analytical reports, validation and verification studies, and certain other notifications to FDA about food testing they conduct under this program. Proposed § 1.1152 would also establish requirements for such submissions, including requirements about what information the submissions must contain. Under section 422(b)(2) of the FD&C Act, the results of food testing conducted under this program must be submitted directly to FDA. To facilitate our meaningful review of such test results, it is critical that we receive supporting information necessary for us to understand the test results and to assess the validity of the underlying testing conducted in that instance. Section 422 of the FD&C Act acknowledges that other information may be sent to FDA under this program, specifically requiring that the model standards we establish under this program must ensure that reports of analyses, which laboratories currently routinely submit to us as testimony in the circumstances described by section 422(b)(1)(B) of the FD&C Act, are certified as true and accurate (see section 422(a)(6) of the FD&C Act).

Proposed § 1.1152(a) through (c) address what information (*e.g.,* test results, sample collection reports, and analytical reports) about the food testing conducted under this program must be submitted to FDA. We have proposed in § 1.1152(d) that accredited laboratories that meet certain requirements may submit abridged analytical reports in lieu of full analytical reports, subject to certain exceptions in proposed § 1.1152(e). Proposed § 1.1152(f) would establish what information must be in an abridged analytical report, and proposed § 1.1152(g) would establish what information must be in a full analytical report. Proposed § 1.1152(h) would require an accredited laboratory using a non-standard method to provide FDA with documentation of the method. By ''documentation'' we mean the method standard operating procedure, or some other document that describes the steps within the method. Proposed § 1.1152(i) would establish requirements for the submission of advance notices of sampling to FDA. Proposed § 1.1152(j) would establish requirements for notifications to FDA of significant changes affecting the accreditation of the accredited laboratory. Proposed § 1.1152(k) would state if FDA does not receive all information required under this section we may consider the related testing to be invalid.

Proposed § 1.1152(a) would require all documentation submitted to us by accredited laboratories under the subpart, which includes test results, sampling reports, analytical reports, validation and verification studies, and certain notifications, to be submitted to us electronically and in English, and to contain certain generally applicable information. More specifically, proposed § 1.1152(a)(1)(i) would require all such notifications, results, reports, and studies submitted to us to include the legal name and street address of the accredited laboratory submitting the information, and would require the documents to identify an appropriate point-of-contact for the accredited laboratory who FDA may contact with questions or comments regarding the notification, result, report, or study, and to include the email address and telephone number of the point of contact. Identification of the accredited laboratory submitting the report would help us identify which accredited laboratory is responsible for the submissions. The identification of a point-of-contact for the accredited laboratory, and the email address and telephone number of the point-of-contact, would help us efficiently conduct any followup communications, as appropriate, with the accredited laboratory that submitted the information. Proposed § 1.1152(a)(1) would also require all documents submitted to FDA under this section to display an identification unique to each test result, report, notification, or study. Of note, proposed § 1.1152(b)(3) would require the test results to cross reference the unique identifiers of all associated reports, notifications, and studies. These requirements are intended to help us quickly identify which submissions are related to each other as we receive them. This provision also reflects a similar provision in ISO/IEC 17025:2017 (Ref. 13) at section 7.8.2, ''Common requirements for reports.'' The last general requirement for submissions, per proposed § 1.1152(a)(iii), is that each submission must be true, accurate, unambiguous, and objective. This requirement would implement the requirement underlying section 422(a)(6)(A)(i) of the FD&C Act that the model standards established by this program for accredited laboratories must ensure that ''reports of analyses are certified as true and accurate,'' and help ensure that accredited laboratories submissions clearly and correctly communicate the information the submission is based on and is intended to communicate. We have tentatively concluded that it is appropriate to establish such a requirement for all submissions under this program to FDA from accredited laboratories.

Proposed § 1.1152(a)(2) would clarify that the accredited laboratory that conducts the analysis of the sample under this program is responsible for the submission of all related notifications, results, reports, and studies to FDA as required by this section.

Proposed § 1.1152(a)(3) provides that if the accredited laboratory that is responsible for the submission becomes aware that any aspect of the submission is inaccurate, the accredited laboratory or sampling service must immediately inform FDA and submit a corrected version. Proposed § 1.1152(a)(3) further provides that such corrections to the notification, result, report, or study must meet the requirements for amendments to reports specified by ISO/IEC 17025:2017 (Ref. 13) section 7.8.8 (incorporated by reference, see § 1.1138(a)(2)). This requirement is important so that we may easily determine when and how a submission has been amended and to which prior submissions the amended submission relates.

Proposed § 1.1152(a)(4) would require that any opinions and interpretations in any notification, result, report, or study submitted to FDA must meet the requirements in ISO/IEC 17025:2017 (Ref. 13) section 7.8.7 (which is incorporated by reference, see proposed § 1.1138(a)(2)), and any statements of conformity to a specification or standard in any notification, result, report, or study submitted to FDA under this subpart must meet the requirements of ISO/IEC 17025:2017 section 7.8.6 (incorporated by reference, see proposed § 1.1138(a)(2)). We have tentatively determined that ISO/IEC 17025:2017 section 7.8.7 provides rules that will be effective at ensuring that opinions and interpretations in submissions to FDA are appropriate and clearly identified. Similarly, we have tentatively determined that ISO/IEC 17025:2017

section 7.8.6 provides rules that will be effective at ensuring that statements of conformity in submissions to FDA under this section are accompanied by appropriate disclosures.

Proposed § 1.1152(b) would establish requirements for submission of test results to FDA. In accordance with section 422(b)(2) of the FD&C Act, proposed § 1.1152(b)(1) provides that the results of all tests conducted under this subpart must be directly submitted to FDA. Proposed § 1.1152(b)(2) specifies that the accredited laboratory that conducted the analysis must submit the results of the food testing to FDA via the website described by § 1.1109, unless FDA has directed a different method of submission in connection with the testing conducted under § 1.1107(a)(2) or (3).

Proposed § 1.1152(b)(3) would require the test results submitted to FDA under this section to be clear, and identify the unique identification of the associated notifications, reports, and studies. These requirements would help us ensure that we can efficiently review the test results and associated submissions as one package.

Proposed § 1.1152(c) would require certain documentation to be submitted with the test results. Specifically, we would require submission to FDA of the following documentation with each test results:

- All sampling plans and sample collection reports related to the food testing conducted, as obtained or developed by the accredited laboratory in accordance with proposed § 1.1149.
- Written documentation of the sampler's qualifications, if proposed § 1.1149(a)(1) requires the accredited laboratory to obtain or develop such documentation.
- The analytical report or reports documenting the analysis related to the food testing. The analytical reports would have to be either abridged or full, depending on whether the accredited laboratory is permitted under proposed § 1.1152(d) to submit abridged analytical reports to FDA. For more information about our proposed requirements for abridged and full analytical reports, see our discussion of proposed § 1.1152(d) through (g) below.
- For any validation studies required by proposed § 1.1151(c)(1), any documentation required by proposed § 1.1151(c)(2), except when the circumstances of proposed § 1.1152(c)(6) (which we discussed in connection with § 1.1138(a)(1)(a), previously) apply with respect to the validation study.
- For any verification studies required by § 1.151(d)(1), the documentation required by § 1.1151(d)(2), except when the circumstances of proposed § 1.1152(c)(6) (which we discussed in connection with § 1.1138(a)(1)(A), previously) apply with respect to the verification study.
- Proposed § 1.1152(c)(6) would establish an important exception to the above two validation and verification study documentation requirements. Proposed § 1.1152(c)(6) provides that we would not require the accredited laboratory to submit the validation or verification study to FDA if the accredited laboratory submitted the validation or verification study to its recognized accreditation body as required by proposed § 1.1138(a)(1) (which addresses certain requirements a laboratory must meet to become accredited by a recognized accreditation body). We have tentatively determined that it is not appropriate under this program for us to duplicate, on a routine basis, the accreditation efforts of accredited laboratory's recognized accreditation body. If the accredited laboratory submitted the validation or verification study to its accreditation body as required by § 1.1138(a)(1), the accreditation body must instead submit to FDA, in lieu of the validation or verification study, a statement that the validation or verification study has been submitted to its recognized accreditation body in accordance with § 1.1138(a)(1), and the accredited laboratory must identify the method, analyte, and matrix that were the subject of the validation or verification study. This information would provide us with sufficient information to determine whether the accredited laboratory's invocation of this exception is appropriate. As discussed in relation to proposed § 1.1113(c), we expect recognized accreditation bodies to substantively review the validation and verification studies they receive from laboratories participating in this program.
- A certification from one or more members of the accredited laboratory's management certifying that the test results, notifications, reports, and studies are true and accurate, and that the documentation includes the results of all tests conducted under this subpart. The certification must specify the name, title, and signature of the certifier or certifiers. The certification that reports are true and accurate is required by section 422(a)(6)(A)(i) of the FD&C Act, but we propose to require the certification to also extend to the test results and related submissions. We propose to include a certification that the laboratory has submitted all tests conducted under this subpart not only because direct submission of test results to FDA is a statutory directive, but because it is vital to the integrity of this program. We expect this certification to help ensure that appropriate laboratory personnel have confirmed the accuracy of the statement.

Note that we do not intend for this certification to mean that the laboratory is attesting that the tested product satisfies regulatory requirements as it is FDA's purview (and not the laboratory's) to determine whether the product meets our regulatory standards. Although the word ''certification'' has such meaning in conformity assessment terminology, we intend a different meaning here. We are using the word, ''certification'' to mean that the management of the laboratory acknowledges that the test was conducted and vouches that the test was conducted properly according to laboratory defined procedures, that the report is true and accurate, and that the report represents all the testing conducted by that laboratory of that particular product for this program.

We propose in § 1.1152(d) that accredited laboratories that meet certain requirements may submit abridged analytical reports under this program in lieu of full analytical reports. We would require full analytical reports to document, in full and step-by-step, the analysis conducted by the accredited laboratory, so that we can engage in a meaningful indepth scientific review of the analysis to determine whether, in that instance, the analysis was valid. For example, we propose in § 1.1152(g) that a full analytical report must include all original compilations of raw data, identify and describe negative and positive quality controls, and include all calculations, among other documentation. Abridged analytical reports, in contrast to full analytical reports, would only need to include certain more limited information describing the analysis.

We view the standards we are creating in this program as relatively rigorous. Accreditation to ISO/IEC 17025:2017, along with the quality assurance, conflict of interest, and other additional requirements contained in this proposed rule, enhance our confidence in the laboratories that participate. In addition, the recognized accreditation bodies will serve an ongoing role monitoring the laboratories they have accredited under this program, helping ensure that the required standards are maintained and serving as an additional observer of the laboratories. For those reasons, and contingent on a positive experience with the accredited laboratories' initial

reports, we would have adequate assurance in the validity of the test results to permit abridged analytical reports, and we tentatively conclude that such abridged analytical reports will provide an adequate basis for FDA to make regulatory decisions.

In addition, we believe that allowing the submission of abridged analytical reports under this food testing program may provide advantages to FDA and the public. We should be able to review abridged analytical reports more quickly than we review full analytical reports, and this may enable us to decide more quickly whether a food safety problem has been addressed and whether to admit an article of food into the United States. This may further allow us to allocate our own laboratory and field resources more efficiently. Furthermore, not requiring accredited laboratories to compile and submit a full analytical report every time they conduct food testing under this program may reduce some of the paperwork and administrative costs of food testing conducted under this program.

At the same time, we note that this laboratory accreditation program would not guarantee that testing by participating laboratories will be valid in every instance. Indeed, a single false negative test result submitted to us under this program could lead us to admit violative food into the United States, or to incorrectly determine that a food safety problem has been adequately addressed, thus potentially harming U.S. consumers. Accordingly, we do not propose to automatically or always allow all accredited laboratories to submit abridged analytical reports under this program. Instead, we have proposed that only accredited laboratories that have fulfilled certain conditions may submit abridged analytical reports to us under this program, and that in certain circumstances we may require such accredited laboratories to submit full analytical reports.

Proposed § 1.1152(e)(1) provides that FDA will occasionally require an accredited laboratory permitted to submit abridged analytical reports to submit to FDA, within 48 hours of the request, the full version of the analytical report. Such a policy will serve the purposes of auditing abridged analytical reports and otherwise protecting the public health and the integrity of this food testing program. By ''occasionally,'' we tentatively conclude that we would not invoke the exception for more than approximately 10 percent of the abridged analytical reports that any given accredited laboratory submits to us per year. We would invoke this exception at our discretion, sometimes on a random basis and sometimes based on risk. With regard to risk, we may be more likely to invoke this requirement where the analysis conducted is for an analyte that presents a relatively high risk to public health (*e.g., Clostridium botulinum*). We may also invoke the exception where something in the abridged laboratory report appears to be amiss (*e.g.,* the method used does not appear to be appropriate). However, we may also invoke the exception on a random basis and in relatively low-risk situations to ensure consistent laboratory performance across the program. At a minimum, we expect to invoke this exception to require each accredited laboratory permitted to submit abridged analytical reports to us to submit at least one full analytical report to us per year. We also note that this provision (along with proposed § 1.1150(d)) would effectively require that accredited laboratories permitted to submit abridged analytical reports to us must still consistently document their analyses internally to such a degree that the accredited laboratory would be able to complete and submit a full analytical report for the analysis to FDA within forty-eight hours of when FDA requests the full analytical report.

We have proposed an additional exception, in proposed § 1.1152(e)(2), to accredited laboratories' ability to submit abridged analytical reports to us under this program. Proposed § 1.1152(e)(2) provides that FDA may require an accredited laboratory that is permitted to submit abridged analytical reports to submit full analytical reports to FDA under this program if such analytical reports relate to an FDA investigation or FDA enforcement proceeding. We may invoke this exception, for example, in the case of a food testing order involving a potentially high risk to public health, or as part of evidence for a hearing under section 423(c) of the FD&C Act, in which case we would have determined that not only does a suspected or identified food safety problem exist but that there is also reasonable probability that the use of or exposure to an article of food will cause serious adverse health consequences or death to humans or animals.

Proposed § 1.1152(d)(1) describes the criteria for an accredited laboratory seeking initial permission to submit abridged analytical reports. Accredited laboratories that are not currently disqualified from submitting abridged analytical reports (see our discussion about disqualification under proposed § 1.1152(d)(6) and (7)) and that are not on probation would become permitted to submit abridged analytical reports to FDA under this program on an ongoing basis after FDA has given notice that all four of the following conditions are fulfilled: (1) The accredited laboratory submits 10 consecutive full analytical reports to FDA under this program, (2) the consecutive full analytical reports include at least one full analytical report relating to each major food testing discipline represented by the methods in the accredited laboratory's scope of accreditation for which it seeks to submit abridged analytical reports, (3) none of the consecutive full analytical reports demonstrate any material substantive shortcoming in the food testing, and (4) the consecutive full analytical reports submitted by the accredited laboratory do not contain repeated administrative deficiencies. Accordingly, when laboratories become accredited under the program they must first submit full laboratory analytical reports under § 1.1152(g), along with the test results and the other documentation required under proposed § 1.1152(c), which FDA will assess to determine whether the four conditions are fulfilled. FDA will track whether the accredited laboratory has fulfilled the four conditions.

As we state above, we are proposing to require that the 10 consecutive full analytical reports includes least one full analytical report relating to each major food testing discipline represented by the methods in the accredited laboratory's scope of accreditation for which the accredited laboratory seeks to submit abridged analytical reports. Three examples of the ''major food testing disciplines'' relevant in this context are microbiology, chemistry, and physical (filth).

Proposed § 1.1152(d)(2) addresses the impact of an accredited laboratory's failure to initially satisfy the four criteria of § 1.1152(d)(1). Under proposed § 1.1152(d)(2)(i), if any analytical report submitted by the accredited laboratory to FDA under this program demonstrates a material substantive shortcoming in the food testing, the accredited laboratory would become disqualified from submitting abridged analytical reports, in accordance with proposed § 1.1152(d)(6)(i). If the 10 full analytical reports submitted by an accredited laboratory are substantively satisfactory but suffer from repeated administrative deficiencies, the accredited laboratory would have another chance to submit consecutive full analytical reports that fulfill the criteria in § 1.1152(d)(1)(i) through (iv). Repeated administrative deficiencies during the second set of 10 full analytical reports would result in

disqualification in accordance with proposed § 1.1152(d)(6)(i).

We propose that a single material substantive shortcoming in the food testing in any of the initial 10 full analytical reports would disqualify an accredited lab, for the period described in § 1.1152(d)(6). We would consider a material substantive shortcoming in the food testing to be incompetence or dishonesty resulting in an invalid test result. FDA will be relying on the food testing conducted under this program to make regulatory decisions, which will impact public health. It is critical that the testing be valid. We have a duty to monitor the testing conducted by an accredited laboratory that submits a full analytical report containing a material substantive shortcoming, so it is appropriate that such a laboratory be disqualified from the privilege of submitting abridged analytical reports (see § 1.1152(d)(6)). Note also that under proposed § 1.1160(a) and (b), if we find a material substantive shortcoming in the food testing, we may consider the analysis to be invalid, and will notify the accredited laboratory, and potentially its recognized accreditation body and the owner or consignee of the food, of the deficiency. For further information on proposed § 1.1160, see section VI.I.3. Note also that under proposed § 1.1146(b), the accredited laboratory would have to treat the feedback as a complaint, in accordance with sections 3.2 and 7.9 of ISO/IEC 17025:2017 (Ref. 13).

Proposed § 1.1152(d)(3) discusses the criteria that laboratories, already submitting abridged analytical reports, must meet in order to begin submitting abridged analytical reports for additional disciplines. Specifically, proposed § 1.1152(d)(3) allows accredited laboratories, not on probation and already permitted to submit abridged analytical reports for at least one major food testing discipline, to submit to abridged analytical reports relating to additional major food testing discipline(s), after FDA has given notice that the following conditions are fulfilled: (1) The accredited laboratory submits to FDA at least one full analytical report for each additional major food testing discipline for which the accredited laboratory seeks to submit abridged analytical reports; (2) there is no material substantive shortcoming in the full analytical report(s) for the additional major food testing discipline(s); and (3) the full analytical reports for the additional major food testing discipline(s) do not contain repeated administrative deficiencies.

Proposed § 1.1152(d)(4) addresses the impact of an accredited laboratory's failure to initially satisfy the three criteria of § 1.1152(d)(3). Under proposed § 1.1152(d)(4)(i), if any analytical report submitted by the accredited laboratory to FDA under this program demonstrates a material substantive shortcoming in the food testing, the accredited laboratory would become disqualified from submitting abridged analytical reports for the food testing discipline that was represented in the analytical report containing the material substantive shortcoming, in accordance with proposed § 1.1152(d)(6)(ii). If any full analytical reports relating to a food testing discipline submitted by an accredited laboratory are substantively satisfactory but suffer from repeated administrative deficiencies, the accredited laboratory would have another chance to submit a full analytical report for that food testing discipline that fulfills the criteria in § 1.1152(d)(3)(i) through (iii). Repeated administrative deficiencies in the second full analytical report would result in disqualification in accordance with proposed § 1.1152(d)(6)(ii).

Proposed § 1.1152(d)(5) provides that if an accredited laboratory, permitted to submit abridged analytical reports for a particular discipline, submits one or more test results, notifications, reports, and/or studies that demonstrate a single material substantive shortcoming in testing or repeated significant administrative deficiencies, the accredited laboratory would be disqualified for that discipline. The period of disqualification should be governed by § 1.1152(d)6)(ii) if the accredited laboratory is permitted to submit abridged analytical reports for other disciplines, and with § 1.1152(d)(6)(i) if not.

For accredited laboratories that currently do not have permission to submit any abridged analytical reports for any disciplines, proposed § 1.1152(d)(6)(i) states that the period of disqualification is either 2 years or until the accredited laboratory submits 20 more satisfactory full analytical reports to FDA under this program, whichever period is longer. During this period of disqualification the accredited laboratory would be ineligible to submit, and to request permission to submit, abridged analytical reports under this program. It is important that this period of disqualification be of sufficient length to establish a meaningful consequence for accredited laboratories that are seeking permission to submit abridged analytical reports but who demonstrate a single material substantive shortcoming in testing or repeated significant administrative deficiencies. We also propose that shortcomings during the disqualification period under § 1.1152(d)(6)(i) would extend the disqualification. Such a policy would help ensure that disqualified laboratories have every incentive to maintain excellent performance during the disqualification period. We propose that any material substantive shortcoming in testing would extend the disqualification period by 6 months, and repeated administrative deficiencies would extend the disqualification period by 2 months.

For an accredited laboratory that currently is permitted to submit abridged analytical reports for at least one food testing discipline and is subject to disqualification for at least one additional food testing discipline, proposed § 1.1152(d)(6)(ii) states that the period of disqualification is either 2 years or until the accredited laboratory submits two or more satisfactory full analytical reports to FDA under this program, whichever period is longer. During this period of disqualification, the accredited laboratory would be ineligible to submit, and to request permission to submit, abridged analytical reports for the testing discipline(s) that is subject to the disqualification period. We also propose that shortcomings during the disqualification period under § 1.1152(d)(6)(ii) would extend the disqualification. Such a policy would help ensure that disqualified laboratories have every incentive to maintain excellent performance during the disqualification period. We propose that any material substantive shortcoming in testing would extend the disqualification period by 6 months, and repeated administrative deficiencies would extend the disqualification period by 2 months.

While the policy in proposed § 1.1152(d)(1) for becoming permitted to submit abridged analytical reports to FDA under this program would apply to newly accredited laboratories that have never been disqualified under proposed § 1152(d)(1), the policy and procedures would be somewhat different for accredited laboratories that have been disqualified. Proposed § 1.1152(d)(7) provides that an accredited laboratory that has fulfilled the criteria under § 1.1152(d)(6), as applicable, and is not on probation, may submit a request (via a portal we would establish on our website) to FDA to submit abridged analytical reports under § 1.1152(d)(1) or (3), as applicable. After FDA receives the request, FDA will consider permitting the accredited laboratory to

fulfill the conditions of proposed § 1.1152(d)(1) or (3), as applicable. If FDA grants permission, and once the conditions described by proposed § 1.1152(d)(1) and (3), as applicable, are fulfilled, FDA will provide notice that the accredited laboratory is permitted to submit to FDA on an ongoing basis abridged analytical reports relating to the discipline(s) for which the conditions are fulfilled.

As we have noted above, if an accredited laboratory submits one or more test results, notifications, reports, and/or studies that demonstrate a single material substantive shortcoming in testing or repeated significant administrative deficiencies we may also take other appropriate action under this proposed rule, including notifying the accredited laboratory's recognized accreditation body (in accordance with proposed § 1.1160) and/or, in more egregious cases, even putting an accredited laboratory on probation or revoking the accredited laboratory's accreditation, if appropriate under proposed § 1.1161.

We request comment on all aspects of our proposed approach to allowing accredited laboratories to submit abridged analytical reports to FDA, including with respect to the practicality and potential consequences of the approach.

Abridged analytical reports, in contrast to full analytical reports, would have to include only certain limited information describing the analysis. Proposed § 1.1152(f) provides that abridged analytical reports must contain:

- All information described by ISO/IEC 17025:2017 (Ref. 13) sections 7.8.2.1(a) through (p) and 7.8.3.1(a) through (d).
- The justification for any modification or deviation to the method(s) of analysis used, and documentation of the accredited laboratory's authorization for the modification or deviation. Although ISO/IEC 17025:2017 (Ref. 13) section 7.8.2.1 requires disclosure of additions to, deviations, or exclusions from the method, we have tentatively determined that abridged analytical reports should also include the justification and authorization for any modification or deviation to the method. This proposed requirement should help us understand whether the method, although modified, is within the accredited laboratory's scope of accreditation, and otherwise help us determine whether we should require submission of the full analytical report version of the abridged analytical report.

Although the information in abridged analytical reports are not sufficient to allow us to engage in a meaningful indepth scientific review of the analysis, and ISO/IEC 17025:2017 section 7.8 appears to relate more to reports laboratories submit to their customers rather than reports laboratories submit to regulatory authorities, we have tentatively determined that the information in abridged analytical reports, as proposed by § 1.1152(f), would be sufficient information for us to make other meaningful decisions related to the analysis, such as whether the method used is appropriate or whether certain risks are present that warrant the submission of the full analytical report. We request comments on what other information should, or should not be, in an abridged analytical report.

Proposed § 1.1152(g) establishes what information full analytical reports submitted under this program must contain. We developed the proposed requirements for what information full analytical reports must contain based on what information we have found is necessary for us to assess the validity of the analyses that private laboratories currently conduct in support of admission of an article of food under section 801(a) of the FD&C Act and to support removal from an import alert through successful consecutive testing. We have tentatively determined that the information we propose full analytical reports must contain is necessary for us to engage in a meaningful indepth scientific review of the analysis to determine that the analysis is valid. Proposed § 1.1152(g) would require full analytical reports to include the following information:

- All information that must be included in an abridged analytical report. As noted previously, this information consists primarily of administrative items and limited substantive information about the analysis performed. It also includes the justification for any modification or deviation to the method(s) of analysis used and documentation of the accredited laboratory's authorization for the modification or deviation.
- Documentation of references for the method or methods of analysis used. Here we simply mean that the package must include the name (*e.g.,* ''Concentration, Extraction, and Detection of Norovirus and Hepatitis A Virus in Molluscan Shellfish'') and source (*e.g.,* AOAC, FDA BAM) of the method used.
- Identification of the analyst or analysts who conducted each analytical step, validation step (if applicable), and verification step (if applicable), including the analyst's or analysts' legal name and signature, and the date each analytical step, validation step (if applicable), and verification step (if applicable) was performed. This information is important because, in accordance with section 422(a)(6)(A)(iv) of the FD&C Act and proposed § 1.1150(b), the analysts must be appropriately qualified.
- Calculations presented in a legible and logical manner. We may need to verify the calculations to verify whether the results of the testing are valid.
- As applicable, references to chromatograms, charts, graphs, observations, photographs of thin layer chromatographic plates, and spectra. References must be in color when appropriate and made in a clear order. These items represent objective evidence and raw data supporting the test results. We may need to review such information to understand and verify the validity of the results of the testing.
- Identification of the source and purity of reference standards used, and, as applicable: Certified reference materials, certified reference cultures traceable to a nationally or internationally recognized type culture collection, including concentration, units preparation, and storage conditions, and reference standard preparation information, including who prepared, date of preparation, expiration date, chemical balance, and solvent used.
- A copy of the label from any immediate container sampled and any additional labeling needed to evaluate the product. Many products are shipped in a variety of different forms, container quantities, and may have varying packaging or labels. The label would likely include important information about the form, unit quantity, or packaging of the food, which we may use to verify that the laboratory analyzed the samples using an appropriate method. The label and labeling would provide additional information which may be helpful to the analysis and our review, such as the ingredient list of the food. For example, if the ingredient list indicates that the food contains an ingredient, additive, or pesticide at a violative level, we may subject to higher scrutiny test results that indicate the food is free from the ingredient, additive, or pesticide or that indicate the food contains the ingredient, additive, or pesticide at a lower level than the ingredient list indicates.
- All original compilations of raw data secured in the course of the analysis, including discarded, unused,

or reworked data with the justification for discarding or reworking such data, corresponding supporting data, and quality control results all identified with unique sample identification, date and time, associated with the test. This information is important for us to understand and to verify the validity of the test results. Furthermore, requiring submission of discarded, unused, or reworked data, along with a justification for discarding, not using, or reworking such data, should discourage testing into compliance.

- Any other relevant additional supporting information such as the storage location of analyzed samples, appropriate attachments such as instrument printouts, computer generated charts and data sheets, and photocopies or original labels for the product analyzed.
- Identification of any software used, including any certificate or certificates of analysis for standards and software used. This information helps us understand the associated test results and verify that the standards used are valid and that the software used is functioning properly.
- The following information about the qualifications of the analyst or analysts who were involved in the analysis conducted under this program, if the accredited laboratory has not previously submitted documentation of the analyst's qualifications to FDA or the analyst's qualifications have significantly changed since the accredited laboratory last submitted documentation of the analyst's qualifications to FDA:
  - The analyst's curriculum vitae;
  - Training records with regards to methods that the analyst is qualified to perform, including the dates of such training and the name of the trainer or training provider;
  - Any other documentation of analyst's ability to perform the method properly in the specific context of the food testing to be conducted, under § 1.1150(b) (*e.g.,* a certificate of completion of a relevant training and/or documentation that the analyst was the investigator for the relevant validation or verification study); and
  - Individual proficiency test worksheets relevant to the analysis being performed.

We invite comment on our proposed requirements for what information full analytical reports must contain. If commenters believe we are proposing to require too much information to be included in full analytical reports, please specifically address in your comments which requirements of § 1.1152(g) we should delete or revise, and why that piece of information is not necessary for us to engage in a meaningful indepth scientific review of the analysis to determine whether the analysis is valid. For commenters who believe we have not proposed sufficient information to be included in full analytical reports, please specify what additional information we should require and why it is critical to our assessment of the analysis and test results.

Proposed § 1.1152(h) would require that if the accredited laboratory conducts the analysis using a method that is not published in a reputable international or national standard or that is otherwise not publicly and readily available, upon request by FDA the accredited laboratory must submit documentation of the method to FDA. If the method used has been published in a reputable international or national standard (*e.g.,* in the Official Methods of Analysis of AOAC International) or the method is otherwise publicly available (readily available, so that a reasonable analyst would be able to easily find the method), we would be able to look up the method ourselves. However, if the method is not published in a reputable international or national standard or otherwise readily publicly available, the accredited laboratory would need to share information about the method with us, if requested, as we may have no other way to access the information. For example, in the case of a method developed by the laboratory, the laboratory would need to submit to us sufficient information about the method for us to understand how the method is applied, such as the method standard operating procedure, or some other document that describes the steps within the method. Such information would be in addition to the validation or verification information that would be required under proposed § 1.1152(c)(4), (5), or (6).

Proposed § 1.1152(i) addresses advance notice of sampling. We are proposing to require advance notice of sampling in certain circumstances as an additional technique to exercise oversight over sampling conducted for food testing in this program. Under proposed § 1.1152(i)(1), if we determine that the sampling conducted by a sampler may materially differ from the sampling documented in the associated sampling plan or sample collection report, or if we determine that the sampling may have been otherwise improper, we may require the accredited laboratory that analyzed the associated sample(s), and other accredited laboratories under this program that have analyzed samples collected by the sampler previously, to request and receive from the sampler, and submit or require the sampler to submit, an advance notice of sampling to the destination specified by the laboratory accreditation program website portal 48 hours before each of the 10 occasions that the sampler will collect a sample that the accredited laboratory will analyze under this program. As we discuss below, we also propose at § 1.1152(i)(2)(ii) and (iii) to be able to specify certain timeframes other than 48 hours and to specify a number other than 10 occasions.

We intend advance notice of sampling to encourage the use of sampling techniques that will allow for a meaningful analysis, by facilitating our observation of sampling and collection of audit samples before we receive the test results with the accompanying sample collection report. Audit samples are samples we collect from the lot or environment at issue, which we then analyze, and compare our test results with the test results of the accredited laboratory. We believe it is reasonable to generally require the notice of sampling to be submitted to us 48 hours prior to collection of the sample(s) to allow us time to determine whether to observe the sampling and/or take an audit sample, and assign appropriate personnel to the task. Note that we may take audit samples (as we currently do) even if we have not required advance notice of sampling.

Proposed § 1.1152(i)(2) elaborates that we may, as appropriate (based on the relevant circumstances): Specify the type of food product or environment that requires advance notice of sampling under this section; determine that an amount of time other than 48 hours in advance is required, to a minimum of 24 hours and up to 7 business days in advance; determine that a number of occasions other than 10 are required, to a minimum of one occasion and up to a maximum of 20 occasions; and notify affected accredited laboratories that submission of additional notices of sampling are not required. We would typically notify affected accredited laboratories that submission of additional notices of sampling are not required after we have observed and/or audit an amount of sampling conducted by the sampler sufficient for us to determine whether the sampler appears to be conducting sampling properly.

Proposed § 1.1152(i)(3) would require that the advance notice of sampling include the following information:

- A unique identification code for the notice of sampling. This would help us identify, review, and record the notification efficiently and would help

us identify associated submissions. The test results would reference the identification numbers of each associated submission.

- The name of the accredited laboratory that will conduct analysis of the sample. This would allow us to, for example, followup with the accredited laboratory that will conduct the analysis, if appropriate, before or during the accredited laboratory's analysis of the samples.
- The name and street address of the sampler that will conduct the sampling. This information will help us organize our review of notices of sampling as they are submitted to us.
- A primary contact (name and phone number) for the sampler. This information would be necessary if we need to contact the sampler. For example, we may need to contact the sampler if we choose to observe or audit the sampling, but the food product or environment at issue is not at the location specified on the notice of sampling.
- The reason(s) why the food product or environment will be sampled. We would want to know, for example, if the sample to be collected will be analyzed by an accredited laboratory with regards to a particular import alert. We expect this information to help us determine whether to observe or audit the sampling.
- The location of the food product or environment that will be sampled, including sufficient information to identify the food product or environment to be sampled. This would help us locate the food product or environment in the case we would want to observe the sampling or take an audit sample.
- As applicable, the U.S. Customs and Border Protection entry and line number(s) and the product code(s) of the food. This would help us identify the food product at issue if we choose to observe or audit the sampling. In the import context, we would want to know the FDA product code. In the domestic context, the U.S. Customs and Border Protection entry and line number(s) would be inapplicable, and we would instead want to know the product code assigned by the manufacturer, packager, labeler, as applicable. In the context of environmental sampling, both items are inapplicable.
- The date and approximate time the sampling will begin. The date must be correct and we would expect the estimated time to be as close to the actual time of the sampling as reasonably possible.

Proposed § 1.1152(j) provides that when any changes occur that affect the accreditation of the accredited laboratory, the accredited laboratory must immediately send FDA, within 48 hours, and the accreditation body that accredited it notice of such changes, a detailed description of such changes, and an explanation of how such changes affect the accreditation of the accredited laboratory. This provision would cover changes in the name or operations of an accredited laboratory, such as the purchase of an accredited laboratory by a company, as well as changes that would cause the accredited laboratory to no longer meet the requirements of this program. We have proposed this requirement in accordance with section 422(a)(1)(C) of the FD&C Act, which requires that, in pertinent part, as a condition of accreditation, as appropriate, accredited laboratories must report to FDA any changes that would affect the accreditation of the laboratory. Proposed § 1.1152(j) would not require accredited laboratories to notify us of changes covered by proposed § 1.1123(c), which requires recognized accreditation bodies to immediately notify us of certain information related to the accreditation status of laboratories they accredit or that have sought their accreditation (*e.g.,* certain changes initiated by the recognized accreditation body, and findings of fraud).

Proposed § 1.1152(k) provides that if FDA does not receive all information required to be submitted to FDA by proposed § 1.1152(a) through (j), FDA may consider the related food testing to be invalid. For example, if we do not receive a validation study when its submission to FDA is required, we would not be able to determine whether the method is appropriate for the intended use; if we do not receive a full analytical report when we require its submission, we would be unable to conduct the necessary indepth scientific review of the analysis to determine whether, in that instance, the analysis was valid; and if we do not receive all the required information about the sampling, we would not be able to determine whether the sample that was analyzed was representative of the food product or environment at issue.

8. What other records requirements must an accredited laboratory meet? (Proposed § 1.1153)

This proposed rule would establish requirements for accredited laboratories to establish, control, and retain records relating to their food testing activities under this program. In addition to meeting the ISO/IEC 17025:2017 records requirements (in accordance with proposed § 1.1146(b)), accredited laboratories would have to meet the additional records requirements of this proposed section.

Proposed § 1.1153(a) would require laboratories that have been accredited to maintain electronically, for 5 years after the date of creation, certain records created and received during their period of accreditation that relate to compliance with this proposed rule. Even if no longer accredited, laboratories that used to be accredited would have an obligation under this proposed rule to maintain records created and received during their period of accreditation. Proposed § 1.1153(a) elaborates that these records include: (1) Documents related to the accredited laboratory's grant (and, if applicable, extensions) of accreditation from its accreditation body; (2) documentation of food testing the accredited laboratory conducted under this program, in accordance with proposed § 1.1150(d); (3) all documents that the accredited laboratory was required to submit to FDA under § 1.1152, and associated correspondence by the accredited laboratory (and its officers, employees, and other agents) with the owner or consignee (and its officer, employees, and other agents) of the tested food product or environment; (4) all requests for food testing from an owner or consignee that would be conducted under this proposed rule; (5) documentation of any internal investigations, internal audits, and corrective actions taken to address any problems or deficiencies related to activities under this proposed rule; (6) documentation related to probation or withdrawal from accreditation under this program; and (7) documentation of changes to its management system or food testing activities that may affect its compliance with this proposed rule. We believe it appropriate to require maintenance of these records for purposes of this proposed rule.

Proposed § 1.1153(b) provides that within 30 days of the receipt of proficiency testing results by the accredited laboratory, the accredited laboratory must submit the proficiency testing results to the recognized accreditation body that accredits the accredited laboratory, and, if the accredited laboratory failed the proficiency test, also to FDA, via the destination specified by the website described by § 1.1109. During our conversations with certain laboratories and accreditation bodies, we received feedback that this proposed rule would benefit from a requirement that proficiency testing results be submitted to the recognized accreditation body that accredits the laboratory. See

''Record of Outreach Sessions on FDA Proposed Rules, Conference call between the FSMA Lab Accreditation Workgroup and the Food Laboratory Alliance, July 21, 2015'' (Ref. 20), and attached meeting minutes. Our understanding is that there is currently no such requirement, and accredited laboratories may decline to submit proficiency test results to their accreditation body. Proficiency test results would provide accreditation bodies with valuable information about the food testing capabilities and proficiencies of the accredited laboratories they accredit. Furthermore, because proficiency testing providers are typically uninterested third parties, there is little risk that submitting the proficiency test results to the accreditation body and potentially FDA would affect the conduct of the proficiency testing. We also believe we may find proficiency testing results helpful as well, particularly if the proficiency testing was unsuccessful and related to food testing results submitted to us under proposed § 1.1152.

Proposed § 1.1153(c) provides that laboratories that have been accredited must make these records available for inspection and copying upon written request of an authorized officer or employee of FDA. The authorized officer or employee of FDA may request that the laboratory submit such records to FDA electronically or that the laboratory make such records promptly available at the physical location of the laboratory or at another reasonably accessible location. If the authorized officer or employee of FDA requests the records be submitted electronically, the records must be submitted electronically not later than 10 business days after the date of the request. However, records related to the immediate notification requirements in § 1.1152(j) must be submitted within 48 hours. If the authorized FDA officer or employee requests records that are maintained in a language other than English, the laboratory must electronically submit an English translation of the records to FDA within a reasonable time. We are not proposing that the records themselves be maintained in English, as we believe such an approach would be unduly burdensome, particularly for foreign laboratories.

Proposed § 1.1153(d) would require laboratories that have been accredited to ensure that significant amendments to records described by proposed § 1.1153(a) and (b) can be tracked to previous and original versions. Proposed § 1.1153(d) further provides that if such a significant amendment is made, both the original document and amended document must be maintained by the laboratory that has been accredited during the time period that the amended document must be maintained. Further, the laboratory must also document the date of amendment, the personnel responsible for the amendment, and a conspicuous indication on the original document stating that the document has been altered and a more recent version of the document exists. This provision is based on ISO/IEC 17025:2017 (Ref. 13) at section 7.5.2. However, section 7.5.2 of ISO/IEC 17025:2017 applies to ''technical records,'' while proposed § 1.1153 applies to a wider category of records.

We acknowledge that the requirements of proposed § 1.1153 may require revisions to contracts and perhaps other documents establishing the scope of a laboratory's authority with respect to granting records access. We nonetheless have tentatively concluded that the records maintenance and access requirements in proposed § 1.1153 are necessary for us to maintain an appropriate degree of oversight over accredited laboratories (in accordance with proposed § 1.1159) and for recognized accreditation bodies to monitor and assess laboratories they accredit.

H. Proposed Provisions About Procedures for Accreditation of Laboratories (Proposed §§ 1.1158 Through 1.1165)

This proposed rule would establish procedures for laboratories to apply for accreditation or relinquish accreditation, and for our oversight of accredited laboratories, including procedures for our review of test results and supporting information, and for probation and revocation of the accreditation of laboratories.

1. How does a laboratory apply for accreditation or modification of its scope of accreditation by a recognized accreditation body? (Proposed § 1.1158)

Proposed § 1.1158 explains how laboratories must apply for accreditation; reinstatement of accreditation or modification of their scope of accreditation; addresses the duration of accreditation; and describes the effects of a denial of an application for accreditation. Section 422 of the FD&C Act establishes a structure whereby FDA recognizes accreditation bodies, who, in turn, accredit laboratories that meet the applicable requirements of the program. As we indicate in proposed § 1.1109, we will maintain a list of recognized accreditation bodies, who may perform accreditation, along with the contact information of these recognized accreditation bodies, so that laboratories would be able to use our website as a resource to find a recognized accreditation body that can assess whether the laboratory is eligible for accreditation.

Proposed § 1.1158(a) provides that a laboratory seeking accreditation must submit its application for accreditation to a recognized accreditation body identified on the website described in proposed § 1.1109. Proposed § 1.1158(a) further provides that the recognized accreditation body will review and assess the application in accordance with the applicable requirements of this program. Proposed § 1.1158(a) also provides that if the laboratory seeking accreditation had its accreditation (in-whole or in-part) withdrawn by a recognized accreditation body, or revoked by FDA the previous time it was accredited under this program, the laboratory must meet the additional requirements specified by proposed § 1.1165 (which addresses the question of how a laboratory requests reinstatement of accreditation).

Proposed § 1.1158(b) clarifies that a laboratory may use documentation of conformance with ISO/IEC 17025:2017, as applicable and supplemented as necessary, in meeting the applicable requirements of this program. For example, if a laboratory is already accredited to ISO/IEC 17025:2017 by a recognized accreditation body, the recognized accreditation body could accept this accreditation as evidence that the laboratory meets the requirements of ISO/IEC 17025:2017 the laboratory must meet under proposed § 1.1138 to become accredited under this proposed rule.

Proposed § 1.1158(c) clarifies that an accredited laboratory's accreditation continues until withdrawn, revoked, or relinquished under this program. It is our understanding that the current practice by accreditation bodies and laboratories is that the laboratory's intent to remain accredited is generally assumed, and the accreditation body continues to accredit the laboratory and conduct assessments and reassessments under that understanding. We seek comment with regards to whether this is correct.

2. How will FDA oversee accredited laboratories? (Proposed § 1.1159)

Proposed § 1.1159 would establish certain requirements related to our oversight of accredited laboratories. Although the recognized accreditation

bodies have primary oversight responsibility over accredited laboratories, we would also exercise some ability to oversee accredited laboratories, via requesting records and, if appropriate, conducting onsite assessments. We note that in contrast to recognized accreditation bodies, under section 422(b)(2) of the FD&C Act, FDA will routinely receive the results of food testing conducted under section 422(b)(1), along with supporting information, which will provide us with information on accredited laboratories' compliance with this program.

Proposed § 1.1159(a) provides that we may assess accredited laboratories at any time to determine whether they continue to comply with the applicable requirements of the program and whether there are any deficiencies in the performance of the accredited laboratory that, if not corrected, would warrant probation or revocation of its accreditation.

Proposed § 1.1159(b) clarifies that, in the course of our evaluation of the performance of an accredited laboratory, we may review any of the following: Records the accredited laboratory would be required to maintain under this proposed rule; records the recognized accreditation body that accredited the accredited laboratory is required to maintain under this proposed rule; information we obtain during an onsite assessment of the accredited laboratory (conducted under proposed § 1.1159(c)); information we obtain during our assessment of the recognized accreditation body that accredited the laboratory; and any other information we obtain, including during FDA's inspections or investigations of one or more owners or consignees of food subject to food testing under this proposed rule.

Proposed § 1.1159(c) provides that our assessment may include our own onsite assessment of the accredited laboratory at any reasonable time, with or without a recognized accreditation body (or its officers, employees, and other agents) present, to assess an accredited laboratory. We would exercise this authority as appropriate to followup on potential problems that come to our attention, for which referral to a recognized accreditation body may be inefficient or otherwise inappropriate, and to otherwise verify compliance with the program. Proposed § 1.1159(d) clarifies that we will also report any of our observations and findings of our assessment to the accredited laboratory's recognized accreditation body.

We seek comments regarding this proposed section and how accreditation bodies and FDA should share oversight of accredited laboratories under this proposed program.

3. How will FDA review submitted test results and analytical reports? (Proposed § 1.1160)

Proposed § 1.1160(a) clarifies that if we find that any test results, analytical report, related documents (for example, the sampling plan, verification studies, and validation studies) or the associated analysis, contains deficiencies or otherwise indicates that any aspect of the food testing is not being conducted in compliance with the program, FDA may consider the analysis to be invalid. We will notify the accredited laboratory that appears to be responsible for the deficiency, and we may also notify the owner or consignee of the food of the deficiency. When we notify the accredited laboratory that appears to be responsible for the deficiency, our notice would be considered a complaint that would be treated in accordance with the laboratory's established procedures for complaints under section 7.9 of ISO/IEC 17025:2017 (Ref. 13). When we notify the laboratory of the deficiency, the laboratory must respond, in writing, to us regarding the deficiency within 30 days or an agreed-upon timeframe, including a statement with respect to how the accredited laboratory intends to address the deficiency, and/or a statement describing the extent to which the laboratory has addressed the deficiency.

Proposed § 1.1160(b) clarifies that we may also report any of our determinations of deficiencies resulting from our review of any test results, reports, and related documents under this rule to the recognized accreditation body that accredits the accredited laboratory.

Proposed § 1.1160(c) clarifies that if the deficiency in the test result, analytical report, and/or the associated analysis demonstrates a material substantive shortcoming in the related food testing or demonstrates repeated administrative deficiencies, FDA will also consider whether disqualification from being eligible for permission to submit abridged analytical reports under proposed § 1.1152(d), and/or other action under this program, is appropriate.

Proposed § 1.1160(d) reiterates the language of section 422(d) of the FD&C Act, stating that nothing in this rule shall be construed to limit our ability to review and act upon information from food testing, including determining the sufficiency of such information and testing. For example, we would typically consider analysis of a non-representative sample to be invalid.

4. When will FDA put an accredited laboratory on probation or revoke the accreditation of a laboratory? (Proposed § 1.1161)

This proposed rule would establish the conditions under which we could put an accredited laboratory on probation or revoke a laboratory's accreditation to conduct food testing under this proposed program. Under this proposal, we could put an accredited laboratory on probation or revoke accreditation only in limited circumstances, including where the recognized accreditation body that accredits the accredited laboratory does not withdraw accreditation itself.

Proposed § 1.1161(a) provides that we may revoke the accreditation (in whole or in part) of an accredited laboratory program for good cause, which may include any of the following reasons: (1) Demonstrated bias or lack of objectivity when conducting food testing under this subpart where the laboratory's recognized accreditation body fails to withdraw accreditation of the laboratory; (2) performance that calls into question the validity or reliability of its food testing under this subpart where the laboratory's recognized accreditation body fails to withdraw accreditation of the laboratory; or (3) other failure to substantially comply with this rule where the laboratory's recognized accreditation body fails to withdraw accreditation of the laboratory.

Proposed § 1.1161(b) provides that if we determine that an accredited laboratory has demonstrated deficiencies in performing its functions that are less serious and more limited than would warrant revocation of accreditation, and it is reasonably likely that the accredited laboratory will be able to correct such deficiencies within a specified period of time, we may temporarily put the laboratory on probation and request that the laboratory take appropriate corrective actions.

Proposed § 1.1161(c) further clarifies that when there are grounds for revocation of accreditation, but the deficiencies are associated with or affect only certain methods within the accredited laboratory's scope of accreditation, we may revoke the accredited laboratory's accreditation only for those affected methods.

Proposed § 1.1161(d) clarifies that our probation of a laboratory's accreditation shall remain in effect until the laboratory demonstrates to our satisfaction that the laboratory has

successfully implemented appropriate corrective actions, or until we determine that revocation of accreditation is warranted.

If we determine that revocation is warranted, under proposed § 1.1161(e) we would notify the laboratory and its recognized accreditation body of the revocation of its accreditation through the issuance of a revocation notice. The revocation notice would state the grounds for revocation; whether the revocation of accreditation is in-whole or in-part, and if it is in-part, to which methods it applies; state the procedures for requesting a regulatory hearing on the revocation under proposed § 1.1173; and state the procedures for requesting reinstatement of accreditation under proposed § 1.1165.

Similarly, if we determine that probation of an accredited laboratory is warranted, under proposed § 1.1161(f) we would notify the laboratory and its recognized accreditation body of the probation, describe the grounds for the probation, and specify other key details, including all deficiencies that must be corrected for FDA to lift the probation. Furthermore, the probation notice would either inform the laboratory that the laboratory has a specified time period to take corrective actions specified by FDA; or request that the laboratory submit a corrective action plan to FDA for FDA's approval that identifies the corrective actions it will take to address deficiencies identified in the notice and identify timeframes for completion.

Proposed § 1.1161(g) provides that we may revoke (in-whole or in-part) the accreditation of the laboratory that has been put on probation if we determine that the laboratory is not implementing appropriate corrective actions.

Proposed § 1.1161(h) reiterates the provision of proposed § 1.1109 that we will provide notice on the website described in proposed § 1.1109 of our probation or revocation of the laboratory's accreditation.

5. What are the consequences if FDA puts an accredited laboratory on probation or revokes the accreditation of a laboratory? (Proposed § 1.1162)

Under proposed § 1.1162(a), if we revoke the accreditation in whole of a laboratory, the laboratory would be immediately ineligible to conduct food testing under this rule. Proposed § 1.1162(a) further provides that if we revoke the accreditation of laboratory in-part, the laboratory is immediately ineligible to use the methods that are subject to the revocation to conduct food testing under this subpart. An accredited laboratory that is put on probation by FDA would be permitted to continue to conduct food testing under this proposed program.

Proposed § 1.1162(b) further provides that, with respect to food testing conducted by the laboratory prior to our revocation of accreditation, we may refuse to consider specific food testing results and associated reports of food testing conducted under this program by the accredited laboratory if the basis for our revocation of accreditation of the laboratory indicates that the specific food testing conducted by the laboratory may not be reliable.

Proposed § 1.1162(c) would require that within 10 business days of the date of issuance of the revocation of accreditation, the laboratory must notify us electronically, in English, of the name of the custodian who will maintain the records required by proposed § 1.1153, and the contact information for the custodian, which must include an email address, and the street address where the records will be located.

Proposed § 1.1162(d) would require that within 10 business days of the date of issuance of the probation or revocation the laboratory notify any owners or consignees for whom it is conducting food testing under this proposed rule that it is on probation or its accreditation has been revoked.

6. What if a laboratory wants to voluntarily relinquish its accreditation? (Proposed § 1.1163)

This proposed rule would offer accredited laboratories a mechanism for voluntarily relinquishing their accreditation. We are proposing certain procedural requirements, similar to those in the accredited third-party certification regulation, that accredited laboratories must follow to relinquish their accreditation. We believe these procedures are necessary to ensure an orderly accreditation relinquishment process and so that we may exercise appropriate oversight and timely update the website described by proposed § 1.1109.

Proposed § 1.1163(a) would require accredited laboratories to notify us electronically, in English, and notify their recognized accreditation body, at least 60 days before voluntarily relinquishing its accreditation in whole or in part. The notice would need to include the date on which relinquishment will occur. If the relinquishment is of the laboratory's accreditation in-whole, the notification must also include the name and contact information of the custodian who will maintain the records required under proposed § 1.1153 after the date of relinquishment or the date accreditation expires, as applicable, and make them available to FDA as required by proposed § 1.1153. The contact information for the custodian must include, at a minimum, an email address and the street address where the records required by proposed § 1.1153 will be located.

For food testing that is subject to proposed § 1.1107(a), we would consider food testing conducted by a laboratory that is not accredited at the time of the food testing to be invalid. This position is in accordance with section 422(b)(1) of the FD&C Act, which requires such food testing to be conducted only by accredited laboratories.

Proposed § 1.1163(b) reiterates that we will provide notice on the website described in § 1.1109 of the voluntary relinquishment of accreditation of the laboratory.

7. What is the effect on accredited laboratories if their accreditation body voluntarily or involuntarily loses its recognition? (Proposed § 1.1164)

Section 422(a)(7)(B) of the FD&C Act provides that we must promptly revoke the recognition of any accreditation body found not to be in compliance with the requirements of section 422 of the FD&C Act, specifying, as appropriate, any terms and conditions necessary for laboratories accredited by such body to continue to perform food testing under this proposed program. We would establish those terms and conditions in § 1.1164 of this proposed rule. Accordingly, proposed § 1.1164(a) provides that when an accreditation body has its recognition revoked, relinquishes its recognition, allows its recognition to expire, or has its application for renewal of recognition denied, a laboratory accredited by the accreditation body must take the following actions (subject to an exception in paragraph (b), which we discuss below): (1) No later than 30 days after FDA issues the notice to the laboratory under proposed § 1.1129, § 1.1130, or § 1.1131 that its accreditation body is no longer recognized, the laboratory submits to FDA documentation of the accredited laboratory's most recent internal audit, which all accredited laboratories would be required to maintain under proposed § 1.1153(a)(5), documentation showing compliance with the conflict of interest requirements in proposed § 1.1147, and documentation of the most recent proficiency test for each test method for which the laboratory is accredited under this subpart, to show compliance with proposed § 1.1138(a)(1)(ii); and (2) no

later than 1 year after FDA issues the applicable notice under proposed § 1.1129, § 1.1130, or § 1.1131 to the laboratory, the laboratory becomes accredited by a recognized accreditation body.

Our review of accredited laboratories' quality assurance records in accordance with proposed § 1.1164(a)(1) would allow us to ensure that the accredited laboratory is in compliance with this rule while it transitions. We believe a period of one year, in accordance with proposed § 1.1164(a)(2), gives the laboratory sufficient time to find a recognized accreditation body and complete its accreditation process while limiting the time the laboratory conducts food testing without the oversight of a recognized accreditation body. We may be more proactive in our oversight of such accredited laboratories during the period they are not subject to the oversight of a recognized accreditation body.

Proposed § 1.1164(b) would establish an exception to the above-described requirements. Under proposed § 1.1164(b), the accredited laboratory may choose to relinquish its accreditation in lieu of meeting the requirements of proposed § 1.1164(a). In such case, the accredited laboratory would have to initiate relinquishment of its accreditation in-whole under proposed § 1.1163 not later than 15 days after FDA issues the applicable notice to the accredited laboratory under proposed § 1.1129, § 1.1130, or § 1.1131, and the relinquishment would need to occur within 90 days. Of note, proposed § 1.1163(a) would typically require an accredited laboratory to submit the relinquishment notice to its recognized accreditation body and to FDA.

However, for a relinquishment initiated in accordance with proposed § 1.1164(b), the accredited laboratory would submit the relinquishment notice under proposed § 1.1163(a) to FDA only, as the accredited laboratory would have no recognized accreditation body at the time.

Generally, if the accredited laboratory does not meet the requirements of either proposed § 1.1164(a) or (b), the accredited laboratory would no longer be in substantial compliance with this proposed rule and its accreditation would generally be subject to revocation under proposed § 1.1161.

8. How does a laboratory request reinstatement of accreditation? (Proposed § 1.1165)

Proposed § 1.1165 describes how a laboratory may obtain reinstatement of its accreditation if we revoked its accreditation, if a recognized accreditation body withdrew its accreditation, or if the laboratory voluntarily relinquished its accreditation.

Proposed § 1.1165(a) addresses how a laboratory may obtain reaccreditation if its accreditation was withdrawn (in whole or in part) by a recognized accreditation body or revoked (in-whole or in-part) by FDA. The laboratory may seek reaccreditation by submitting a new application for accreditation (in-whole or in-part, as applicable) under proposed § 1.1158 to a recognized accreditation body. Proposed § 1.1165(a) further provides that the laboratory must also: (1) Notify us, before it submits the new application for accreditation to the recognized accreditation body, that the laboratory will be submitting a new application for accreditation to the recognized accreditation body, including in the notification the legal name of the laboratory, valid contact information for the laboratory, the legal name of the recognized accreditation body the laboratory will be submitting the application to, and the date that the laboratory expects to submit the new application for accreditation; and (2) demonstrate, to the satisfaction of the recognized accreditation body it is submitting the new application to, that the grounds for the withdrawal of accreditation have been resolved and that the laboratory has implemented measures to prevent such grounds from recurring. If the laboratory's accreditation had been withdrawn by a recognized accreditation body, the requirement to notify us would allow us to check whether the laboratory had been recently denied reaccreditation by a different recognized accreditation body, which could possibly indicate whether the laboratory is successively seeking approval of accreditation without changing its practices. Alternatively, if we revoked the laboratory's accreditation, we may want to contact the recognized accreditation body to which the laboratory is applying, to, for example, explain to the accreditation body why we found it necessary to revoke the laboratory's accreditation.

Proposed § 1.1165(b) addresses how a laboratory may obtain reaccreditation after it voluntarily relinquishes its accreditation. A laboratory that voluntarily relinquished its accreditation may seek reinstatement of accreditation by submitting a new application for accreditation under proposed § 1.1158 to a recognized accreditation body.

I. Proposed Provisions About Requesting FDA Reconsideration, FDA Internal Review, or Regulatory Hearings of FDA Decisions Under This Rule (Proposed §§ 1.1171 Through 1.1174)

This proposed rule would establish requirements and procedures an accreditation body would have to follow to request that we reconsider our decision to deny its application for recognition, to request we internally review our decision to deny its request to reconsider its application for recognition, and to request a regulatory hearing on our decision to take adverse action with respect to its recognition. This proposed rule would also establish requirements and procedures a laboratory would have to follow to request a regulatory hearing on our decision to take an adverse action with respect to the laboratory's accreditation. Further, this proposed rule would establish requirements and procedures owners and consignees would have to follow to request a regulatory hearing on a food testing order. Finally, this proposed rule would establish procedures for the conduct of such reconsiderations, internal reviews, and regulatory hearings.

1. How does an accreditation body request reconsideration by FDA of a decision to deny its application for recognition, renewal, or reinstatement? (Proposed § 1.1171)

This proposed rule would establish procedures for an accreditation body to seek reconsideration of our denial of its application for recognition, renewal of recognition, or reinstatement of recognition.

The procedures described by proposed § 1.1171 require submission of the request for reconsideration within 10 business days of the issuance of such denial. The request for reconsideration must be submitted to us electronically, in English, and in accordance with the procedures described in the notice of denial. The request must also be signed by the accreditation body or by an individual authorized to act on its behalf. Within a reasonable time after we complete our review and evaluation of the request for reconsideration and the supporting information submitted, we would notify the requestor through the issuance of the recognition upon reconsideration or through the issuance of a denial of recognition upon reconsideration. We note that should FDA issue a denial after a request for reconsideration, the accreditation body would be able to request the review of such decision under 21 CFR 10.75.

2. How does an accreditation body or laboratory request a regulatory hearing on FDA's decision to revoke the recognized accreditation body's recognition or revoke the accredited laboratory's accreditation? (Proposed § 1.1173)

This proposed rule explains the procedures that would be used for challenges to our revocation of an accreditation body's recognition or our revocation of a laboratory's accreditation.

Under proposed § 1.1173(a), an accreditation body whose recognition was revoked or a laboratory whose accreditation was revoked (or an individual authorized to act on the accreditation body's or laboratory's behalf) may submit a request for a regulatory hearing, under part 16, on the revocation. The request must be submitted within 10 business days of the date of revocation. Written notices of revocation will contain all the elements required by § 16.22 and will thereby constitute the notice of an opportunity for hearing under part 16.

Under proposed § 1.1173(b), the request for a regulatory hearing must be submitted with a written appeal that responds to the bases for our decision described in the written notice of revocation together with any supporting information upon which the requestor is relying. The request, appeal, and supporting information must be submitted to us electronically, in English, and in accordance with the procedures described in the notice of revocation.

Proposed § 1.1173(c) makes clear that the submission of a request for a regulatory hearing under this rule will not operate to delay or stay the effect of our decision to revoke recognition of an accreditation body or to revoke accreditation of a laboratory unless we determine that delay or a stay is in the public interest.

Under proposed § 1.1173(d) and (e), the presiding officer for a regulatory hearing under this proposed rule will be designated after the request for a regulatory hearing is submitted to us. The presiding officer may deny a request for regulatory hearing under this proposed rule under 21 CFR 16.26(a) when no genuine or substantial issue of fact has been raised.

Proposed § 1.1173(f) states that if a hearing request is granted, the hearing will be held within 10 business days after the date the request was filed or, if applicable, within a timeframe agreed upon in writing by requestor and the presiding officer and FDA.

The presiding officer must conduct the hearing under part 16, except that, under § 16.5(b), the procedures for a regulatory hearing described in part 16 apply only to the extent that such procedures are supplementary and not in conflict with the procedures specified for the conduct of regulatory hearings under this rule. The following requirements of part 16 are inapplicable to regulatory hearings conducted under this rule: § 16.22 (Initiation of a regulatory hearing); § 16.24(e) (Timing) and (f) (Contents of notice); § 16.40 (Commissioner); § 16.60(a) (public process); § 16.95(b) (Administrative decision and record for decision); and § 16.119 (Reconsideration and stay of action).

Proposed § 1.1173(f)(3) clarifies that a decision by the presiding officer to affirm the revocation of recognition or the revocation of accreditation that served as the basis for the request for a regulatory hearing is considered a final Agency action for purposes of 5 U.S.C. 702.

3. How does an owner or consignee request a regulatory hearing on a food testing order? (Proposed § 1.1174)

This proposed rule explains the procedures that would be used for challenges to our issuance of a food testing order.

Proposed § 1.1174(a) provides that no later than 24 hours after we issue the food testing order, the owner or consignee who is the subject of the food testing order may submit a request for a regulatory hearing, conducted under part 16, on the food testing order. The food testing order will contain all of the elements required by § 16.22(a) and will thereby constitute the notice of an opportunity for hearing under part 16.

Proposed § 1.1174(b) provides that the request for a regulatory hearing must be submitted with a written appeal that responds to the bases for our determinations described in the food testing order, together with any supporting information upon which the requestor is relying. The request, appeal, and supporting information must be submitted in English to the address specified in such notice and in accordance with the procedures described therein. The request, appeal, and supporting information may be submitted electronically.

Proposed § 1.1174(c) states that the presiding officer for the regulatory hearing will be designated after a request for the regulatory hearing is submitted to FDA. Proposed § 1.1174(c) states that the presiding officer may deny a request for regulatory hearing under this rule under § 16.26(a).

Proposed § 1.1174 provides that if the presiding officer grants a request for a regulatory hearing, the hearing will be held within 2 business days after the date the request was filed or, if applicable, within a time frame agreed upon in writing by requestor and the presiding officer and FDA. Furthermore, the presiding officer may require that a hearing conducted under this proposed rule be completed within one business day, as appropriate. We believe that it is in the interest of both public health and the owner and consignee that regulatory hearings on food testing orders be resolved quickly and efficiently. As noted, however, this proposed rule would allow for flexibility by allowing the requestor, the presiding officer, and FDA to agree on an alternative timeframe for holding the hearing.

Proposed § 1.1174(e)(3) provides that the presiding officer must conduct the hearing in accordance with part 16, except that, consistent with § 16.5(b), the procedures for a regulatory hearing described in part 16 apply only to the extent that such procedures are supplementary and not in conflict with the procedures specified for the conduct of regulatory hearings under this proposed rule. Accordingly, the following requirements of part 16 would be inapplicable to regulatory hearings conducted under this proposed rule: The requirements of §§ 16.22 (Initiation of a regulatory hearing); 16.24(e) (timing) and (f) (contents of notice); 16.26(a) (denial of hearing); 16.40 (Commissioner); 16.42(a) (presiding officer); 16.60(a) (public process); 16.95(b) (Administrative decision and record for decision); and 16.120 (Reconsideration and stay of action) of this chapter.

Proposed § 1.1174 clarifies that a decision by the presiding officer to affirm the testing order would be considered a final Agency action under 5 U.S.C. 702.

J. Proposed Provisions About Electronic Records and Public Disclosure Requirements Under This Rule (Proposed §§ 1.1199 Through 1.1200)

1. Are electronic records created under this rule subject to the electronic records requirements of part 11 of this chapter? (Proposed § 1.1199)

We are proposing to exempt from the requirements of 21 CFR part 11 records that meet the definition of electronic records in § 11.3(b)(6) and are established or maintained to satisfy the requirements of this proposed rule. We believe it would be unnecessarily burdensome to require such records to

comply with the requirements in part 11. However, records that are established or maintained to satisfy the requirements of this program but that also are required under other applicable statutory provisions or regulations remain subject to part 11 of this chapter. This is the same approach we took when finalizing our rule on accredited third-party certification.

2. Are the records obtained by FDA under this rule subject to public disclosure? (Proposed § 1.1200)

We understand that notifications, records, and reports required under this program will often contain commercially sensitive information. Information submitted to the Agency, including reports and notifications submitted under proposed §§ 1.1123 and 1.1152, becomes an Agency record. We are proposing to clarify at proposed § 1.1200 that records under this proposed rule are subject to 21 CFR part 20, which provides protections for trade secrets and confidential commercial information from public disclosure (see, *e.g.,* § 20.61, ''Trade secrets and commercial or financial information which is privileged or confidential''). This is the same approach we took when finalizing our rule on accredited third-party certification.

K. Proposed Revisions to 21 CFR Part 1, Subpart M

On November 27, 2015, FDA published in the **Federal Register** a final rule, ''Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications'' (accredited third-party certification regulation), to implement section 808 of the FD&C Act on accreditation of third-party certification bodies to conduct food safety audits and to certify that eligible foreign entities (including registered food facilities) and the human and animal food produced by such entities meet applicable FDA food safety requirements (80 FR 74570). The accredited third-party certification regulation, codified at part 1, subpart M, establishes the requirements for how an accredited third-party certification body must conduct a food safety audit—*i.e.,* a regulatory audit or a consultative audit that is conducted to determine compliance with the applicable requirements of the FD&C Act, FDA regulations, and for consultative audits, also includes conformance with industry standards and practices.

Under the accredited third-party certification regulation, an accredited third-party certification body must use an accredited laboratory when sampling and analysis is conducted for a regulatory audit (§ 1.651(c)(2)). Laboratories may be accredited in accordance with ISO/IEC 17025:2005 or another laboratory accreditation standard that provides at least a similar level of assurance in the validity and reliability of the sampling methodologies, analytical methodologies, and analytical results (§ 1.651(b)(3)). For consistency between the accredited third-party certification regulation and this rulemaking, we propose to revise § 1.651(b)(3) to cite the current version of the ISO/IEC laboratory accreditation standard by striking ''ISO/IEC 17025:2005'' and inserting ''ISO/IEC 17025:2017.'' This would mean that a laboratory accredited under this proposed rule, if finalized, would be among the laboratories that a third-party certification body could use to perform analysis.

In addition, we propose to remove the option in § 1.651(b)(3)(ii) for an accredited third-party certification body to use a laboratory accredited under a standard other than ISO/IEC 17025 when sampling and analysis is conducted for a regulatory audit. In developing this proposed rule, we have gathered additional information about the number and capacity of laboratories accredited under ISO/IEC 17025 to conduct food testing. Based on this information and in the interest of consistency, we are proposing to remove the option in § 1.651(b)(3)(ii) for an accredited third-party certification body to use a laboratory accredited under a standard other than ISO/IEC 17025 when sampling and analysis is conducted for a regulatory audit.

Finally, we are proposing clarifying edits to §§ 1.651(b)(3) and 1.651(c)(2) make it clear that the requirement to use a laboratory accredited under ISO/IEC 17025 to conduct food testing applies only to the analysis of the sample and not the collection of the sample itself. As discussed previously in this rule, we are not at this time proposing requirements for the accreditation of samplers.

We solicit comment on the effect, if any, of these proposed changes on an accredited third-party certification body's ability to meet the requirements in §§ 1.651(b)(3) and 1.651(c)(2) to use an accredited laboratory when analyzing samples collected during a regulatory audit.

L. Proposed Revisions to 21 CFR Part 11

As we discussed in section VI.K.2, we are proposing to exempt from the requirements of part 11 records that meet the definition of electronic records in § 11.3(b)(6) and are established or maintained to satisfy the requirements of this proposed rule. Consistent with that provision, we are making a conforming change in part 11 by adding a paragraph (p) to § 11.1 to that effect. The new paragraph (p) would also clarify that records that satisfy the requirements of this program but that also are required under other statutory provisions or regulations remain subject to part 11 to the extent that they are not separately exempted.

M. Proposed Revisions to 21 CFR Part 16

As we discussed in section VI.J, at proposed §§ 1.1171 through 1.1174 we have proposed to establish procedures for regulatory hearings for certain actions we may take under this proposed rule. We are proposing a conforming change to part 16, which describes procedures for regulatory hearings, to add revocation of recognition of an accreditation body, revocation of accreditation of a laboratory, and issuance of a food testing order to the list of actions for which a regulation hearing under part 16 may be held. The affected section is § 16.1.

N. Proposed Revisions to 21 CFR Part 129

As noted above at section VI.B.1, where we discuss proposed § 1.1107, the regulations on the processing and bottling of bottled drinking water at part 129 contain an explicit testing requirement that addresses an identified or suspected food safety problem and that therefore would have to be conducted by a laboratory accredited under this proposed rule. Specifically, § 129.35(a)(3)(i) contains a requirement that a source previously found to contain *E. coli* will be considered negative for *E. coli* after five samples collected over a 24-hour period from the same sampling site that originally tested positive for *E. coli* are tested and found to be *E. coli* negative. Section 129.35(a)(3)(i) contains additional routine testing requirements that do not address an identified or suspected food safety problem and are not subject to this proposed rule.

Section 129.35(a)(3)(iii) provides that the analysis of samples taken under § 129.35(a)(3)(i) ''may be performed for the plant by competent commercial laboratories (*e.g.,* Environmental Protection Agency and State-certified laboratories).'' Section 129.35(a)(3)(iii) has the potential to conflict with this proposed rule because section 422(b)(1)(A)(i) of the FD&C Act requires food testing conducted in response to the explicit testing requirement that ''address[es] an identified or suspected food safety problem'' in § 129.35(a)(3)(i)

to be conducted by a laboratory accredited under this proposed program. A laboratory may qualify as a ''competent commercial laboratory'' but not be accredited under this proposed program. Accordingly, we are proposing a conforming change to § 129.35(a)(3)(iii) to clarify that the explicit testing requirement in § 129.35(a)(3)(i) that addresses an identified or suspected food safety problem must be conducted under this proposed program, which would require, in pertinent part, the laboratory conducting the testing to be accredited under this proposed program.

VII. Proposed Effective Date and Implementation Steps

The effective date is the date that provisions in the rule affect the current Code of Federal Regulations. We propose that the effective date of this rule would be 60 days after publication of the final rule in the **Federal Register**.

FDA intends to implement this program as expeditiously as practicable. Implementation of this laboratory accreditation program will necessarily need to occur in a stepwise fashion. We would announce when, after the effective date, we are prepared to accept applications for recognition from accreditation bodies. We would announce when we have recognized a sufficient number of accreditation bodies, at which point laboratories could then apply to the recognized accreditation bodies for accreditation. FDA would publish in the **Federal Register**, at least 6 months in advance, notice that we have attained sufficient laboratory capacity such that owners/consignees in the circumstances described in proposed § 1.1107 will be required to utilize laboratories accredited under this program.

VIII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order (E.O.) 12866, E.O. 13563, E.O. 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). E.O.s 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). E.O. 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' We believe that this proposed rule is not a significant regulatory action as defined by E.O. 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because a significant number of testing laboratories are small businesses and due to initial one-time costs we find that the proposed rule may 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.

Summary of Costs and Benefits

The proposed rule, if finalized, would require that testing of food in certain circumstances be performed by an accredited laboratory (participating lab) accredited to the proposed standards by a recognized accreditation body (participating accreditation body), and for the results to be submitted to us. The costs of the proposed rule, if finalized, would be incurred primarily by participating accreditation bodies, participating labs, shell-egg producers, sprouts producers, bottled water manufacturers, and owners and consignees of human and animal food offered for import covered by the proposed rule. We would incur costs to establish and maintain the program for recognizing accreditation bodies hoping to participate in our program, assessing participating accreditation bodies and participating labs, and for reviewing associated documents and reports. The present value of the cost of the proposed rule, if finalized, would range from $34 million to $78 million when discounted by 7 percent over 10 years. When discounted by 3 percent over 10 years the present value of the cost would range from $39 million to $92 million.

The proposed rule, if finalized, would generate some quantified and unquantified benefits. Quantified benefits include cost-savings from the proposed clarifications of the process for compiling, submitting and reviewing analytical reports for human and animal food offered for import covered under the proposed rule, and a reduced burden from the proposed abbreviated reporting requirements. In addition, there would be savings from fewer false positive test results. We anticipate a reduction in the number of foodborne illnesses from fewer false negative test results for human and animal food offered for import covered under the proposed rule and for shell eggs, sprouts, bottled water, and other food subject to specific testing requirements covered under the proposed rule. Unquantified benefits could include fewer illnesses from deterring unsafe manufacturing practices by all entities affected by the proposed rule. The present value of the quantified benefits of the proposed rule, if finalized, would range from $26 million to $81 million when discounted by 7 percent over 10 years. When discounted by 3 percent over 10 years the present value of the quantified benefits would range from $32 million to $98 million. We expect that specific test reporting requirements would result in more accurate analytical reports and reporting.[7]

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. In table 1, we provide the Regulatory Information Service Center and Office of Information and Regulatory Affairs Consolidated Information System accounting information.

[7] There are currently no reporting requirements for tests of shell eggs, sprouts, or bottled water.

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE [1]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year	$7.56	$3.71	$11.52	2016	7	10	Cost savings.
	7.56	3.71	11.52	2016	3	10	Cost savings.
Annualized Quantified					7		
					3		
Qualitative	Reduced risk of food-related illness from improper test reporting practices imported human and animal food covered under the proposed rule, and shell eggs, sprouts and bottled water and other tests subject to specific testing requirements. Reduced risk of food-related illness from unsafe food manufacturing practices.						
Costs:							
Annualized Monetized $millions/year	$6.73	$4.64	$9.27	2016	7	10	
	6.76	4.73	9.28	2016	3	10	
Annualized Quantified					7		
					3		
Qualitative							
Transfers:							
Federal Annualized Monetized $millions/year					7		
					3		
From/To	From:			To:			
Other Annualized Monetized $millions/year					7		
					3		
From/To	From:			To:			

Effects:
State, Local or Tribal Government: None.
Small Business: Potential impacts on laboratories currently not accredited to ISO/IEC 17025 that would participate in the labs program described by the proposed rule.
Wages: None.
Growth: None.

[1] The lower bound equals the 5th percentile and the upper bound equals the 95th percentile.

In line with E.O. 13771, in table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon.

TABLE 2—E.O. 13771 SUMMARY TABLE

[in $ millions 2016 dollars discounted over an infinite time horizon] [1]

	Primary (7%)	Lower bound (7%)	Upper bound (7%)	Primary (3%)	Lower bound (3%)	Upper bound (3%)
Present Value of Costs	$100.29	$56.49	$144.54	$216.92	$115.07	$319.32
Present Value of Cost Savings	101.85	71.15	134.87	237.65	172.25	307.92
Present Value of Net Costs	−1.56	−57.43	53.51	−20.73	−149.76	110.77
Annualized Costs	7.02	3.95	10.12	6.51	3.45	9.58
Annualized Cost Savings	7.13	5.17	9.24	7.13	5.17	9.24
Annualized Net Costs	−0.11	−3.99	3.84	−0.62	−4.49	3.32

[1] The lower bound equals the 5th percentile and the upper bound equals the 95th percentile.

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. 21) and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

IX. Analysis of Environmental Impact

We have carefully considered the potential environmental effects of this action. We have concluded, under 21 CFR 25.30(h), that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required (Ref. 22).

X. 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 (PRA) (44 U.S.C. 3501–3520). This analysis provides a description of these

provisions and an estimate of the annual reporting and recordkeeping burden associated with the proposed rule. 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.

We invite 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: Laboratory Accreditation for Analyses of Foods.

Description: As mandated by section 422 of the FD&C Act, we are establishing of a program for the testing of food by accredited laboratories; establishing a publicly available registry of recognized accreditation bodies and accredited laboratories; and establishing procedures for reporting any changes affecting the recognition of such accreditation bodies or accreditation of such laboratories.

Description of Respondents: Respondents to the collection of information are accreditation bodies seeking recognition from FDA, recognized accreditation bodies, laboratories seeking accreditation from recognized accreditation bodies, and accredited laboratories. We estimate the burden of the information collection as follows:

Reporting Burden: Consistent with figures discussed in our Preliminary Regulatory Impact Analysis (PRIA) (see Section II.D, Number of Entities), we estimate a total of 66 respondents. We estimate that five to 80 accreditation bodies would apply for FDA recognition under the rule, with a mean distribution of 17.5 accreditation bodies. For this analysis we round up to 18. Similarly, we estimate of a mean of 48 laboratories will participate in the program, for a total of 66 respondents to the information collection. The reporting burden includes a burden of 8,820 hours associated with one-time submissions. In this analysis, we annualize the one-time submission burden using a 3-year period horizon and zero percent discount rate, for an annualized one-time reporting burden of 2,940 hours. Cumulatively, this results in a total annual reporting burden of 15,049.05 hours, as reflected in table 3.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR part 1, subpart R citation; IC activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
§§ 1.1113/1.1128(a); Accreditation bodies (ABs) application for recognition (one-time submission)	18	1	18	20	360
§ 1.1123(b) and (c); ABs—general reporting requirements	18	12	216	* .5	108
§ 1.1128(b); ABs—application for renewal of recognition	18	1	18	3.6	64.8
§§ 1.1138 and 1.1158; laboratories—submission of application for accreditation (one-time submission)	48	1	48	20	960
§ 1.1152(c)(1) and (2); laboratories—Submission of sampling plan, sample collection report, and sampler qualifications	48	88.48	4,247	1.75	7,432
§ 1.1152(d); laboratories—qualification to submit abridged analytical reports (one-time submission)	48	10	480	2	960
§ 1. 1152(c)(3); laboratories—abridged analytical reports submissions	48	88.48	4,247	1.16	4,927
§ 1.1152(c)(4) and (5); laboratories—validation and verification studies submissions	9	1	9	†.25	2.25
§ 1.1152(i); laboratories—advance notice of sampling submissions	48	3	144	1.5	216
§ 1.1152(j); laboratories—immediate notification	48	1.5	72	.25	18
§§ 1.1165; 1.1171; 1.1173; and 1.1174; requests in response to FDA action	1	1	1	1	1
Total					15,049.05

* (30 mins.)
† (15 mins.)

Proposed § 1.1128(a) would require accreditation bodies that wish to be recognized to submit an application to FDA that demonstrates their qualifications (those qualifications are specified by proposed § 1.1113) to accredit laboratories under this rule. We estimate this process would take one analyst between 40 and 80 hours to compile all the relevant information, prepare for an assessment, and complete initial application process, and submit the application. For this analysis we assume a middle value of 60 hours. Also for this analysis, we use a 3-year period horizon and zero percent discount rate to convert the one-time submission burden to an annualized figure (*i.e.,* 60 hours ÷ by 3 = 20 hours). Annually this results in 360 hours of burden for initial applications submitted by 18 accreditation bodies (18 applications × 20 hours per application), as reflected in row 1.

Proposed § 1.1123 would require a recognized accreditation body to report information, including significant changes affecting its accreditation program or the accreditation status of laboratories it accredits, and ensure FDA has access to these and other records. We estimate recognized accreditation bodies would incur a burden of 1 hour per month, or 12 hours per year, complying with both the reporting requirements of proposed § 1.1123 and the recordkeeping requirements of proposed § 1.1124. For this analysis, we identify recordkeeping and reporting burdens separately and assume 6 of the 12 hours (*i.e.,* 30 minutes per month) would be spent meeting the reporting requirements of § 1.1123. Annually, this results in 108 hours (18 recognized accreditation bodies × 6 hours per year), as reflected in row 2.

Proposed § 1.1128(b) would require accreditation bodies to apply for renewal of recognition at least every 5 years. We believe renewal would take less time than an initial application because much of the information will have already been compiled and therefore assume between 20 and 40 hours. For this analysis we use a middle value and calculate that each recognized accreditation body will spend 30 hours every 5 years to complete and submit an application for renewal of its

recognition. This results in 6 hours per year (30 hours ÷ 5 years) for each accreditation body. Because we use a 3-year period horizon and zero percent discount rate for this analysis, we annualize that figure to three-fifths or 3.6. We multiply this figure by 18 accreditations bodies for a total of 64.8 hours annually for the submission of renewal of applications (18 applications × 3.6 hours per application), as reflected in row 3.

Proposed § 1.1158 would require a laboratory seeking accreditation to submit an application for accreditation to a recognized accreditation body, demonstrating that it meets the requirements for accreditation under the proposed rule (those requirements are specified by proposed § 1.1138). We estimate 48 laboratories will apply and assume it would take one analyst an average of 60 hours to compile all the relevant information, however we regard the burden as a one-time burden and therefore have annualized it by 3 years (20 hours annually). This results in an annual reporting burden for initial applications by 48 laboratories would be 960 hours (48 applications × 20 hours per application), as reflected in row 4.

Proposed § 1.1152(a) through (i) would require accredited laboratories to submit testing results of testing conducted under the program and include supporting documentation. However, as discussed in our supporting statement, only a percentage of that testing would be defined as information collection under the PRA. For this analysis we assume a mean figure of 4,197, as the basis for factoring a corresponding information collection burden. This figure is derived using lower and upper bound estimates of submissions we expect under the rule. To allow for adjustment and potential increase we have added a count of 50 submissions for a total of 4,247.

Proposed § 1.1152(c)(1) would require accredited laboratories to obtain, or develop, and submit a sample collection plan and sample collection report (the contents of which would be prescribed by proposed § 1.1149) with each test result. Under proposed § 1.1152(c)(2), laboratories would also be required to include documentation of the sampler's qualifications the first time the sampler collects a sample, or when the sampler's qualifications have significantly changed. We assume that it would take 30 minutes to 1 hour to compile a sampling plan, 30 minutes to one hour to compile a sample collection report, and an average of 10 to 20 minutes to obtain the sampling plan, sample collection report, and sampler's credentials. Using a middle value of 1.5 hours to generate the sampling plan and the sample collection report, and a middle value of 15 minutes (.25 hours) to obtain those two documents and documentation of the sampler's qualifications, we calculate a total of time per test results of 1.75 hours (1.5 + .25). When multiplied together the total reporting burden for the submission of sampling plans, sample collection reports, and sampler credential requirements (48 accredited laboratories × 88.48 sampling plans and sample collection reports × 1.75 hours) is 7,432 hours, as reflected in row 5.

Proposed § 1.1152(d) would allow accredited laboratories to qualify to submit abridged analytical reports in lieu of full analytical reports. At this time we expect this would be a one-time burden, but we may revisit this assumption in the future based on actual disqualification rates if the proposed rule is finalized and implemented. We assume that each accredited laboratory would submit 10 consecutive full analytical reports to qualify to submit abbreviated reports. We also assume accredited laboratories spend 4 to 8 hours to compile and submit a full analytical report, and we use the middle value of 6 hours for this analysis. For initial or one-time burdens we use a 3-year period horizon and zero percent discount rate to convert the one-time burden to an annualized figure (2 hours). When multiplied together, this results in a total reporting burden for the accredited laboratories to qualify to submit abridged analytical reports of 960 hours (48 laboratories × 10 full analytical reports each × 2 hours per analytical report), as reflected in row 6.

After an accredited laboratory qualifies to submit abridged analytical reports, we assume it would submit abridged analytical reports to us thereafter. We may revisit this assumption in the future based on actual disqualification rates if the proposed rule is finalized and implemented. We estimate the burden to compile and submit an abridged analytical report to be between 25 percent and 33 percent of the burden of compiling and submitting a full analytical report, and we use a middle value of 29 percent here. Thus, using these figures we calculate it would take an accredited laboratory 1.74 hours to compile and submit an abridged analytical report (29 percent × 6 hours). This results in an annual total reporting burden for the 48 accredited laboratories to compile and submit abridged analytical reports of approximately 4,927 hours (48 laboratories × 88.48 abridged analytical reports × 1.16 hours per abridged analytical report), as reflected in row 7.

The proposed rule would also require the participating lab to submit verification and validation studies to FDA as part of an analytical report, or to an accreditation body as a prerequisite for participation in the labs program. The ISO/IEC 17025 standard requires the use of validated and verified methods for testing foods. However, the proposed rule, if finalized, would require additional verification studies over and above the requirements of ISO/IEC 17025. Additional studies may include information to verify that a method previously validated for a specific food item is also valid for a different food item, in what is called a ''matrix extension.'' We estimate that the additional time burden of requiring laboratories to submit verification studies such as matrix extensions under this proposed rule to be a middle value of approximately 3 percent of the time burden incurred by laboratories to maintain accreditation to ISO/IEC 17025 (the PRIA estimates a range of 1 percent to 5 percent). In the PRIA we also note that internal FDA experts suggest that between 5 percent and 30 percent of import food testing results require verification studies such as matrix extensions. We use a middle value of 17.5 percent for this analysis.

With regard to validation requirements, we assume that methods used to test shell eggs, sprouts, and bottled water are either already validated or the costs to doing so would be included in the costs to maintain accreditation to the ISO/IEC 17025 standard. Consequently, we assume that shell eggs, sprouts, and bottled water producers would incur no burden from this requirement beyond the burden of the proposed rule's requirements to meet the validation requirements of ISO/IEC 17025.

We estimate the time required to perform a matrix extension is a middle value of 34 hours (the PRIA estimates a range of 22 to 46 hours). We do not distinguish between the burden of reporting the study and the burden of conducting the study. We assume 25 percent of the 34 hours (8.5 hours) is attributable to the associated reporting burden. Because we estimate that the additional time burden of requiring laboratories to submit verification studies such as matrix extensions under this proposed rule would be approximately 3 percent of the time burden incurred by laboratories to maintain accreditation to ISO 17025, we multiply 8.5 hours by 3 percent to get the additional reporting burden of .255 hours (15.3 minutes, which we round to

15 minutes, which is .25 hours) per study imposed by the verification study submission requirements of the proposed rule. To estimate the number of test results that would require matrix extensions, we multiply the number of import testing results that would be submitted to us under this rule annually that are subject to PRA requirements (50) by the share of test results submitted to us for import food testing that require matrix extensions (17.5 percent), for a total of 8.75 matrix extensions per year. This equates to an average of .17708 matrix extensions per accredited laboratory (8.5 ÷ 48). Because the number of respondents and the annual responses per respondent in a PRA analysis must be whole numbers, we instead estimate that nine accredited laboratories (48 × .17708, rounded to 9 from 8.5) will submit one full verification study to FDA annually. Therefore, the annual reporting burden of requiring the submission of validation and verification studies under this proposed rule is 2.25 hours (9 accredited laboratories × 1 verification studies × .25 hours per study), as reflected in row 8.

Proposed § 1.1152(i) would provide that, under certain circumstances, FDA may require one or more accredited laboratories to submit an advance notice of sampling to FDA before each of the next several occasions that the sampler will a collect a sample that the accredited laboratory will analyze under this program. We assume that it would take a laboratory analyst between 1 and 2 hours to compile the required information and submit the information, and we assume that between one percent and five percent of all test results submitted annually under this program would be subject to the notice of sampling requirement. For this analysis we assume middle values of 1.5 hours and three percent, respectively. Thus, we estimate that 127.41 test results (4,247 × 3%) would require submission of advance notice of sampling under the proposed rule. For this analysis we assume that each of the estimated 48 accredited laboratories would be required to submit three notices of advance sampling annually under the proposed rule (127.41 ÷ 48 = 2.65; rounded to 3). Thus, the annual reporting burden on accredited laboratories due to the proposed advance notice of sampling requirement would be 216 hours (48 laboratories × 3 advance notices of sampling × 1.5 hours), as reflected in row 9.

Proposed § 1.1152(j) would require accredited laboratories to notify FDA and the accreditation body of any changes that affect the laboratory's accreditation. Note, however, that under § 1.1123(c), recognized accreditation bodies also have a duty to immediately notify FDA of changes in an accredited laboratory's status. Thus, an accredited laboratory is not required to notify FDA of changes that fall under § 1.1123(c). To be conservative we estimate that every lab that participates will have some change about which it must notify its accreditation body, and for half of those changes the accredited laboratory will also need to notify FDA. We estimate it will take an accredited laboratory 15 minutes per notification. Thus we estimate the burden associated with § 1.1152(j) would be 18 hours (48 accredited laboratories × 1.5 notifications × 0.25 hours per notification), as reflected in row 10.

Proposed §§ 1.1165, 1.1171, 1.1173, and 1.1174 provide for requests to FDA. Specifically, § 1.1165 provides for requests for reinstatement of accreditation; § 1.1171 provides for requests for reconsideration of denials; and §§ 1.1173 and 1.1174 provide for requests for hearings. Because this is a new collection, we are estimating a cumulative total of 1 respondent and 1 burden hour, as reflected in row 11, however we invite specific comment in this regard. Upon implementation of any final rule, we will reevaluate our burden estimate in light of overall submissions to the Agency and public comments received.

Recordkeeping Burden: Recordkeeping requirements associated with the proposed rule include a one-time burden of 1,366.05 hours and annual burden of 41,912.74 hours. In this analysis, we annualize the one-time recordkeeping burden using a 3-year period horizon and zero percent discount rate, for an annualized one-time recordkeeping burden of 455.35. Cumulatively, we estimate an annual recordkeeping burden under this proposed rule of 43,278.79 hours, as reflected in table 4.

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN

Proposed 21 CFR part 1, subpart R; IC activity	Number of record-keepers	Number of records per record-keeper	Total annual records	Average burden per record-keeping (in hours)	Total hours
§§ 1.113 and 1.1118; recordkeeping associated with ISO/IEC 17011	18	1	18	1	18
§ 1.1124; ABs—additional recordkeeping requirements	18	1	18	6	108
§ 1.1138; laboratories—becoming accredited to ISO/IEC 17025 (one-time)	5	1	5	91.06	455.35
§ 1.1146; laboratories—maintaining ISO/IEC 17025 accreditation	48	1	48	889.53	42,697.44
Total					43,278.79

Proposed § 1.1113 and § 1.1118 would require accreditation bodies to meet the requirements of ISO/IEC 17011 to be recognized. While ISO/IEC 17011 includes recordkeeping requirements, as noted above we estimate that all of the 18 accreditation bodies that would become recognized under the proposed rule currently adhere to ISO/IEC 17011. We therefore regard these activities as usual and customary, however we include a place holder of one response and one burden hour for each respondent, as reflected in row 1.

Proposed § 1.1124, however, provides for the maintenance of certain records in addition to those required by ISO/IEC 17011. We estimate recognized accreditation bodies would incur a burden of 12 hours per year to comply with both the recordkeeping requirements of proposed § 1.1124 and the reporting requirements of proposed § 1.1123. For this analysis, we identify the recordkeeping and reporting burdens separately, assuming six of those 12 annual hours would be spent complying with the recordkeeping requirements of proposed § 1.1124. Thus, the annual recordkeeping burden for the 18 recognized accreditation bodies to meet the additional recordkeeping requirements of proposed § 1.1124 would be 108 hours, as reflected in row 2.

Proposed § 1.1138 would require laboratories to meet certain requirements of ISO/IEC 17025, including its recordkeeping requirements, to be accredited under the proposed rule. We estimate that between two to eight laboratories not

currently accredited to ISO/IEC 17025 would become accredited. We use a middle estimate of five laboratories and also estimate that it would take a mean of 91.06 hours for the associated recordkeeping activities. This results in an annualized burden of 455.35, as reflected in row 3.

Proposed § 1.1146 would require laboratories to maintain conformance with ISO/IEC 17025, including its recordkeeping requirements. Based on available data, and as discussed in our PRIA, we estimate a mean of 889.53 hours for this recordkeeping. This results in an annual burden of 42,697.44 hours, as reflected in row 4.

The proposed rule also affects currently approved information collections. Information collection provisions found in part 11 of our regulations are currently approved under OMB Control No. 0910–0303. Information collection provisions found in part 129 of our regulations are currently approved under OMB Control No. 0910–0658. Although no new information collection or no material modification is being introduced by the proposed rule, upon implementation of any final rule we will reevaluate our burden estimates for these collections accordingly. Finally, information collection provisions found in part 16 of our regulations are exempt from OMB review and approval under the PRA, as the information collection occurs during the conduct of an official administrative action (see 5 CFR 1320.4(a)(2)).

To ensure that comments on this 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 PRA, the Agency has 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. We will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

XI. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13132. We have determined that the proposed rule does not contain policies that 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. Accordingly, we have tentatively concluded that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

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.

* 1. FDA Memorandum, ''Assessment of DWPE Sampling and Analysis Data to Determine what Portion of Sampling and Analysis of Food under DWPE is Conducted by Accredited Entities.'' Toni Morales and Tyler Scandalios, FDA. November 20, 2018.
* 2. Congressional Hearing, ''The Safety of Food Imports: Fraud & Deception in the Food Import Process; Hearings Before the Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations.'' September 10, 1998. *https://www.gpo.gov/fdsys/pkg/CHRG-105shrg51562/pdf/CHRG-105shrg51562.pdf*. Accessed on June 17, 2019.
* 3. ''Private Laboratory Guidance,'' ORA Laboratory Manual, Vol. III, Section 7, document number III–07. FDA. January 30, 2013. *https://www.fda.gov/media/81810/download*. Accessed on June 17, 2019.
4. ''ISO/IEC 17025:2005 ''General Requirements for the Competence of Testing and Calibration Laboratories'' (withdrawn). International Organization for Standardization/International Electrotechnical Commission. May 2005. Copies are available from the International Organization for Standardization, Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland, or on the internet at *https://www.iso.org/standard/39883.html,* or may be viewed on the internet through, *https://www.surveymonkey.com/r/KFJMZ67* or may be examined at the Dockets Management Staff (Ref. Docket No. FDA–2019–N–3325 and/or RIN 0910–AH31).
*5. ''Action Plan for Import Safety.'' Interagency Working Group on Import Safety. November 2007. *http://www.itagc.org/docs/ITAGC-2010-11-10-FDA-4.pdf*. Accessed June 17, 2019.
* 6. GAO Report, ''Federal Oversight of Food Safety: FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out Is Critical (GAO–08–435T).'' Government Accountability Office. January 29, 2008. *https://www.gao.gov/assets/120/118821.pdf*. Accessed on June 17, 2019.
* 7. GAO Report, ''Food Safety: FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements are Needed (GAO–04–246).'' Government Accountability Office. January 30, 2004. *https://www.gao.gov/assets/250/241327.pdf*. Accessed on June 17, 2019.
* 8. FDA Draft Guidance for Industry, ''Submission of Laboratory Packages by Accredited Laboratories'' (withdrawn). FDA. January 16, 2009.
9. ''Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals, An Aid to Interpretation of ISO/IEC 17025:2005.'' AOAC International. April 2015. Copies are available from AOAC International, 2275 Research Blvd., Ste. 300, Rockville, MD 20850–3250, USA, or on the internet at *http://www.aoac.org/aoac_prod_imis/AOAC/AOAC_Member/PUBSCF/ALACCCF/ALACC_M.aspx,* or may be examined at the Dockets Management Staff (Ref. Docket No. FDA–2019–N–3325 and/or RIN 0910–AH31).
* 10. ''IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Requirements and Procedures for Evaluation of a Single Accreditation Body.'' International Accreditation Forum/International Laboratory Accreditation Cooperation. January 2018. Available at *https://ilac.org/publications-and-resources/joint-ilac-iaf-series/*. Accessed on June 17, 2019.
* 11. ''OMB Circular A–119: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities.'' Office of Management and Budget. January 2016. *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/inforeg/inforeg/revised_circular_a-119_as_of_1_22.pdf*. Accessed on June 17, 2019.
* 12. ''ISO/IEC 17011:2017(E), ''Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies.'' International Organization for Standardization/International Electrotechnical Commission. November 2017. Copies are available from the International Organization for Standardization, Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland, or on the internet at *https://www.iso.org/standard/67198.html,* or may be examined at the Dockets Management Staff (Ref. Docket No. FDA–2019–N–3325 and/or RIN 0910–AH31).
13. ISO/IEC 17025:2017(E), ''General Requirements for the Competence of

Testing and Calibration Laboratories.'' International Organization for Standardization/International Electrotechnical Commission. November 2017. Copies are available from the International Organization for Standardization, Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland, or on the internet at *https://www.iso.org/standard/66912.html,* or may be examined at the Dockets Management Staff (Ref. Docket No. FDA–2019–N–3325 and/or RIN 0910–AH31).

* 14. Meeting Minutes, ''Sampling Accreditation Discussion with ABs.'' FDA. November 13, 2017.

* 15. ''R103—General Requirements: Proficiency Testing for ISO/IEC Laboratories.'' American Association for Laboratory Accreditation. September 19, 2013. *https://portal.a2la.org/requirements/R103_2013.pdf.* Accessed on June 17, 2019.

*16. ''Accreditation Requirements: ISO/IEC 17025 Testing Laboratories (Non-Forensics).'' ANSI/ASQ National Accreditation Board. October 9, 2018. *https://anab.qualtraxcloud.com/ShowDocument.aspx?ID=8160.* Accessed on June 17, 2019.

17. ISO/IEC 17043:2010, ''Conformity Assessment—General Requirements for Proficiency Testing.'' International Organization for Standardization/International Electrotechnical Commission. February 2010. Copies are available from the International Organization for Standardization, Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland, or on the internet at *https://www.iso.org/standard/29366.html,* or may be examined at the Dockets Management Staff (Ref. Docket No. FDA–2019–N–3325 and/or RIN 0910–AH31).

* 18. ''Methods, Method Verification and Validation,'' ORA Laboratory Manual, Vol. II, Section 2, document number ORA–LAB.5.4.5. FDA. August 29, 2014. *https://www.fda.gov/media/73920/download.* Accessed on June 17, 2019.

* 19. FDA Memorandum, ''Guidelines for the Validation of Chemical Methods for the FDA FVM Program, 2nd Edition.'' FDA Foods and Veterinary Medicine Science and Research Steering Committee. May 19, 2015. *https://www.fda.gov/media/81810/download.* Accessed on June 17, 2019.

* 20. Meeting Record, ''FSMA Lab Accreditation/Food Laboratory Alliance Meeting Record August 21, 2015.'' FDA. July 21, 2015.

* 21. FDA. Accreditation of Laboratories to Conduct Food Testing: Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis, 2019. *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

* 22. FDA Memorandum. ''Proposed Rule: Amendment of 21 CFR parts 1, 11, 16, and 129 to Establish a Program for Laboratory Accreditation for Analyses of Foods as Required by FD&C Act.'' Leah D. Proffitt, FDA, June 14, 2019.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements, Incorporation by reference.

21 CFR Part 11

Computer technology, Reporting and recordkeeping requirements.

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 129

Beverages, Bottled water, Food packaging, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 1, 11, 16, and 129 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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

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, 343, 350c, 350d, 350e, 350j, 350k, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 373, 374, 381, 382, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271.

■ 2. In § 1.651, revise paragraphs (b)(3) and (c)(2) to read as follows:

§ 1.651 How must an accredited third-party certification body conduct a food safety audit of an eligible entity?

* * * * *

(b) * * *

(3) When, for a regulatory audit, sampling and analysis is conducted, the accredited third-party certification body must use a laboratory that is accredited in accordance with ISO/IEC 17025:2017 to perform the analysis.

* * * * *

(c) * * *

(2) The audit must include records review prior to the onsite examination; an onsite examination of the facility, its process(es), and the food that results from such process(es); and where appropriate or when required by FDA, environmental or product sampling and analysis. When, for a regulatory audit, sampling and analysis is conducted, the accredited third-party certification body must use a laboratory that is accredited in accordance with paragraph (b)(3) of this section to conduct the analysis. The audit may include any other activities necessary to determine compliance with applicable food safety requirements of the Federal Food, Drug, and Cosmetic Act and FDA regulations, and, for consultative audits, also includes conformance with applicable industry standards and practices.

* * * * *

■ 3. Add subpart R, consisting of §§ 1.1102 through 1.1200, to read as follows:

Subpart R—Accreditation of Laboratories to Conduct Food Testing

General Provisions

Sec.

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1.1171 How does an accreditation body request reconsideration by FDA of a decision to deny its application for recognition, renewal, or reinstatement?
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1.1199 Are electronic records created under this subpart subject to the electronic records requirements of part 11 of this chapter?
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Subpart R—Accreditation of Laboratories To Conduct Food Testing

General Provisions

§ 1.1102 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this subpart, unless otherwise specified. For the purposes of this subpart, the following definitions also apply:

Accreditation means a determination by a recognized accreditation body that a laboratory meets the applicable requirements of this subpart to conduct food testing under this subpart using one or more methods of analysis.

Accredited laboratory means a laboratory that a recognized accreditation body has determined meets the applicable requirements of this subpart and has been accredited to conduct food testing using one or more methods of analysis under this subpart.

Analyst means an individual who analyzes samples.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)).

Food testing and *testing of food* means the analysis of food product samples or environmental samples.

Food testing order means an order issued by FDA under §§ 1.1107(a)(2) and 1.1108 requiring food testing to be conducted under this subpart by or on behalf of an owner or consignee.

Owner or consignee means any person with an ownership or consignment interest in:

(1) The food product or environment that is the subject of food testing conducted under § 1.1107(a)(1);

(2) Food product or environment that is the subject of the order issued under § 1.1107(a)(2);

(3) The food product or environment that is the subject of food testing conducted under § 1.1107(a)(3);

(4) The article of food for which food testing is being conducted under § 1.1107(a)(4); or

(5) The food subject to an import alert for which food testing is conducted under § 1.1107(a)(5).

Recognition means a determination by FDA that an accreditation body meets the applicable requirements of this subpart and is authorized to accredit laboratories under this subpart.

Recognized accreditation body means an accreditation body that FDA has determined meets the applicable requirements of this subpart and is authorized to accredit laboratories under this subpart.

Representative sample means a sample that accurately, to a scientifically acceptable degree, represents the characteristics and qualities of the food product or environment that the sample was collected from.

Sampler means an individual or individuals who perform sampling.

Scope of accreditation refers to the methods of analysis for which the accredited laboratory is accredited. References in this subpart to accreditation ''in-whole'' refers to all methods in the accredited laboratory's scope of accreditation and references to accreditation ''in-part'' refers to only certain methods in the accredited laboratory's scope of accreditation.

§ 1.1103 Who is subject to this subpart?

(a) *Accreditation bodies.* An accreditation body is subject to this subpart if it has been recognized by FDA, or is seeking to be recognized by FDA, to accredit laboratories to conduct food testing under this subpart.

(b) *Laboratories.* A laboratory is subject to this subpart if it has been accredited by a recognized accreditation body, or is seeking to be accredited by a recognized accreditation body, to conduct food testing under this subpart.

(c) *Owners and consignees.* An owner or consignee is subject to this subpart if they are required to use an accredited laboratory to conduct food testing under this subpart.

General Requirements of This Subpart

§ 1.1107 Under what circumstances must food testing be conducted under this subpart by an accredited laboratory?

(a) Food testing must be conducted under this subpart whenever such testing is conducted by or on behalf of an owner or consignee:

(1) In response to explicit testing requirements that address an identified

or suspected food safety problem, which are contained in the following provisions:

(i) *Sprouts.* 21 CFR 112.146(a), (c) and (d);

(ii) *Shell eggs.* 21 CFR 118.4(a)(2)(iii), 118.5(a)(2)(ii) and (b)(2)(ii), and 118.6(a)(2) and (e); and

(iii) *Bottled drinking water.* 21 CFR 129.35(a)(3)(i) (for the requirement to test five samples from the same sampling site that originally tested positive for *Escherichia coli*);

(2) As required by FDA in a food testing order;

(3) To address an identified or suspected food safety problem and presented to FDA as part of evidence for a hearing under section 423(c) of the Federal Food, Drug, and Cosmetic Act prior to the issuance of a mandatory food recall order, as part of a corrective action plan under section 415(b)(3)(A) of the Federal Food, Drug, and Cosmetic Act submitted after an order suspending the registration of a food facility, or as part evidence submitted for an appeal of an administrative detention order under section 304(h)(4)(A) of the Federal Food, Drug, and Cosmetic Act.

(4) In support of admission of an article of food under section 801(a) of the Federal Food, Drug, and Cosmetic Act;

(5) To support removal from an import alert through successful consecutive testing;

(b) When food testing is conducted under paragraph (a) of this section, analysis of samples must be conducted by accredited laboratories that are accredited for the appropriate analytical method or methods by a recognized accreditation body.

(c) Food testing conducted on articles of food offered for import into the United States under section 801(a) of the Federal Food, Drug, and Cosmetic Act pursuant to paragraph (a)(4) or (a)(5) of this section may only be conducted after the articles offered for import have arrived in the United States unless FDA has determined, and responded in writing to the owner/consignee, that a sample(s) taken prior to arrival is or would be representative sample(s) of such article(s) offered for import into the United States.

§ 1.1108 When and how will FDA issue a food testing order?

(a) FDA may require the owner or consignee of an article of food to conduct food testing, or to have food testing conducted on their behalf, under this subpart to address an identified or suspected food safety problem related to the article of food.

(b) The food testing order will specify the food product or environment to be tested; whether the food testing may be conducted using an accredited laboratory that is owned, operated, or controlled by the owner or consignee; the timeframe in which the food testing must be conducted; and the manner of the food testing, such as the methods that must be used.

(c) The food testing order will contain all the elements required by § 16.22(a) of this chapter and will thereby constitute the notice of an opportunity for hearing under part 16 of this chapter. An affected owner or consignee may request a regulatory hearing on a food testing order, pursuant to § 1.1174 of this subpart.

§ 1.1109 How will FDA make information about recognized accreditation bodies and accredited laboratories available to the public?

(a) Except as provided by paragraph (b) of this section, FDA will place on its website a list of:

(1) Recognized accreditation bodies, including for each recognized accreditation body: The name, contact information, and duration of recognition of the recognized accreditation body;

(2) Accreditation bodies that have their recognition revoked by FDA or are put on probation, and accreditation bodies that have relinquished their recognition or have allowed their recognition to expire, including for each accreditation body: The name of the accreditation body, whether FDA revoked recognition of the accreditation body or put the recognized accreditation body on probation, or whether the accreditation body relinquished its recognition or allowed its recognition to expire, and the date of the probation, revocation, relinquishment, or expiration;

(3) Laboratories accredited under this subpart, including for each laboratory: The name, contact information, and scope of accreditation of the accredited laboratory, and the name and contact information of the accreditation body that accredits the accredited laboratory; and

(4) Laboratories that have been put on probation or have had their accreditation withdrawn or revoked (in-whole or in-part) by a recognized accreditation body or by FDA, or have relinquished their accreditation (in-whole or in-part), including for each laboratory: The name of the laboratory, whether a recognized accreditation body or FDA put the laboratory on probation, or withdrew or revoked the accreditation of the laboratory, or whether the laboratory relinquished its accreditation, and the date of the probation, withdrawal, revocation, or relinquishment.

(b) In the interest of national security, FDA, in coordination with the Secretary of Homeland Security, may determine an alternate time, manner, and form in which the list described in paragraph (a) of this section is made publicly available.

Recognition of Accreditation Bodies

§ 1.1113 What requirements must an accreditation body meet to become recognized by FDA?

To become recognized by FDA, an accreditation body seeking recognition by FDA must:

(a) Be a full member of the International Laboratory Accreditation Cooperative (ILAC) and a signatory to the ILAC Mutual Recognition Arrangement (MRA) that has demonstrated competence to ISO/IEC 17011:2017;

(b) Demonstrate it complies with ISO/International Electrotechnical Commission (IEC) 17011:2017, ''Conformity assessment—Requirements for accreditation bodies accrediting conformity assessment bodies,'' Second edition, November 2017. The Director of the Federal Register approves this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. The approved material is available for inspection at Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 301–827–6860, and is available from International Organization for Standardization (ISO), Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland; Telephone 41 22 749 01 11, *https://www.iso.org/home.html.* It is also available for inspection 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 *www.archives.gov/federal-register/cfr/ibr-locations;* and

(c) Demonstrate that it possesses sufficient scientific/technical expertise to be able to:

(1) Review the validation and verification studies required by § 1.1138(a)(1), including reviewing the verification studies for fitness for purpose;

(2) Assess an accredited laboratory's determination under § 1.1148(a)(2) that no proficiency testing program is available or practicable for a particular method of analysis; and

(3) Assess whether the comparison program proposed by the accredited laboratory under § 1.1148(a)(2) would provide the recognized accreditation

body with the ability to monitor the quality of the laboratory's performance to a degree comparable to a proficiency test.

(d) Demonstrate it is capable of complying with all requirements under this subpart for recognized accreditation bodies.

Requirements for Recognized Accreditation Bodies

§ 1.1118 What are the general requirements for recognized accreditation bodies to remain recognized?

To remain recognized, a recognized accreditation body must:

(a) Be a full member of the International Laboratory Accreditation Cooperative (ILAC) and a signatory to the ILAC Mutual Recognition Arrangement (MRA) that has demonstrated competence to ISO/IEC 17011:2017;

(b) Meet, with respect to activities under this subpart, the requirements of ISO/IEC 17011:2017, which is incorporated by reference (see § 1.1113(b)); and

(c) Demonstrate that it possesses sufficient scientific/technical expertise to be able to:

(1) Review the validation and verification studies required by § 1.1138(a)(1), including reviewing the verification studies for fitness for purpose;

(2) Assess an accredited laboratory's determination under § 1.1148(a)(2) that no proficiency testing program is available or practicable for a particular method of analysis; and

(3) Assess whether the comparison program proposed by the accredited laboratory under § 1.1148(a)(2) would provide the recognized accreditation body with the ability to monitor the quality of the laboratory's performance to a degree comparable to a proficiency test.

(d) Comply with all of the additional requirements under this subpart for recognized accreditation bodies.

§ 1.1119 What requirements apply to how a recognized accreditation body must protect against conflicts of interests?

(a) In addition to meeting the impartiality and conflict of interest requirements of § 1.1118(b), the recognized accreditation body must:

(1) Ensure that the recognized accreditation body (and its officers, employees, or other agents involved in accreditation activities) does not own or have a financial interest in, manage, or otherwise control any laboratory (or any affiliate, parent, or subsidiary) it accredits; and

(2) Prohibit, subject to the exceptions in paragraph (b) of this section, officers, employees, or other agents involved in accreditation activities of the recognized accreditation body from accepting any money, gift, gratuity, or other item of value from any laboratory they accredit or that is seeking their accreditation that conducts food testing.

(b) The prohibited items of value specified in paragraph (a)(2) of this section do not include:

(1) Money representing payment of fees for accreditation services or reimbursement of direct costs associated with an onsite assessment or reassessment of the laboratory; or

(2) Lunch of de minimis value provided during the course of an assessment or reassessment and on the premises where the assessment or reassessment is conducted, if necessary to facilitate the efficient conduct of the assessment or reassessment.

(c) The financial interests of the spouses and children younger than 18 years of age of a recognized accreditation body's officers, employees, and other agents involved in accreditation activities are considered the financial interests of such officers, employees, and other agents involved in accreditation activities.

§ 1.1120 How must a recognized accreditation body evaluate laboratories seeking accreditation and oversee the performance of laboratories it accredits?

(a) A recognized accreditation body must conduct an initial assessment of a laboratory seeking accreditation in accordance with the requirements of § 1.1118(b), to determine whether the laboratory meets the requirements of § 1.1138.

(b) Subject to the exception in paragraph (c) of this section, the initial assessment must be conducted onsite, although certain assessment activities may be conducted remotely if it will not aid the assessment to conduct them onsite.

(c) If, within the previous 2 years, the accreditation body conducted an onsite assessment of the laboratory in accordance with ISO/IEC 17011:2017 to assess whether the laboratory meets the requirements of ISO/IEC 17025:2017, then the initial assessment under this section:

(1) May be conducted remotely, and

(2) Need only address whether the laboratory meets the requirements of § 1.1138(a)(1) and (c).

(d) A recognized accreditation body must oversee the performance of a laboratory it accredits in accordance with the applicable requirements of § 1.1118(b), except as otherwise provided by this subpart, to determine whether the accredited laboratory continues to meet the applicable requirements of this subpart.

(e) The assessment of the sample of the scope of accreditation of the accredited laboratory, which the recognized accreditation body must conduct at least every 2 years in accordance with § 1.1118(b), must be conducted onsite, although certain assessment activities may be conducted remotely if it will not aid the assessment to conduct them onsite.

(f) If the recognized accreditation body conducted the initial assessment of the laboratory remotely in accordance with paragraph (c) of this section, the recognized accreditation body must conduct its first assessment of the sample of the scope of accreditation of the accredited laboratory no later than 2 years after the recognized accreditation body last conducted an onsite assessment of the laboratory in accordance with ISO/IEC 17011:2017 to assess whether the laboratory meets the requirements of ISO/IEC 17025:2017.

(g) The reassessment at the end of the accredited laboratory's accreditation cycle, which the recognized accreditation body must conduct in accordance with § 1.1118(b), must be conducted onsite, although certain assessment activities may be conducted remotely if it will not aid the assessment to conduct them onsite.

(h) Any assessments conducted by a recognized accreditation body that are in addition to the assessments referred to in paragraphs (a), (e), and (g) of this section may be conducted remotely if it will not aid the assessment to conduct them onsite.

§ 1.1121 What appeal procedures must a recognized accreditation body provide for appeals of decisions to not grant accreditation?

A laboratory may appeal a decision by the recognized accreditation body to not grant the accreditation (in-whole or in-part) that the laboratory sought, and the recognized accreditation body must consider the appeal in accordance with the requirements of § 1.1118(b). In addition to meeting the requirements of § 1.1118(b) relating to appeals, the recognized accreditation body must make the appeals procedures publicly available. It must also establish and implement written procedures to use a competent person(s) who may or may not be external to the recognized accreditation body, who is free from bias or prejudice and has not participated in the accreditation decision and is not the subordinate of a person who participated in the accreditation decision, to review and decide appeals.

§ 1.1122 When must a recognized accreditation body withdraw or reduce the scope of the accreditation of a laboratory, and when may a recognized accreditation body put an accredited laboratory on probation?

(a) *Grounds for withdrawal of accreditation.* A recognized accreditation body must withdraw the accreditation of a laboratory it accredits when the accredited laboratory substantially fails to comply with this subpart.

(b) *Grounds for probation.* If a recognized accreditation body determines that an accredited laboratory it accredits demonstrates deficiencies in performing its functions under this subpart that are less serious than those identified in paragraph (a) of this section, and it is reasonably likely that the accredited laboratory will be able to correct such deficiencies within a specified period of time, the recognized accreditation body may temporarily put the accredited laboratory on probation.

(c) *Withdrawal in-part.* When there are grounds for withdrawal of accreditation of an accredited laboratory that the recognized accreditation body accredits, but the deficiencies affect only certain methods within the accredited laboratory's scope of accreditation, the recognized accreditation body may withdraw the accredited laboratory's accreditation for only for those affected methods.

(d) *Records request associated with withdrawal of accreditation or probation.* To assist the recognized accreditation body in determining whether a withdrawal of accreditation (in-whole or in-part) or probation is warranted under paragraph (a), (b), or (c) of this section, the recognized accreditation body may require from a laboratory that it accredits the submission of records that the accredited laboratory is required to maintain under § 1.1153.

(e) *Notification of withdrawal of accreditation.* The recognized accreditation body must notify the laboratory of the withdrawal (in-whole or in-part) of the laboratory's accreditation, and such notification must:

(1) Specify whether the withdrawal of accreditation is in-whole or in-part, and if it is in-part, to which method or methods it applies;

(2) Describe the grounds for withdrawal; and

(3) State the procedures for appealing the withdrawal.

(f) *Notification of probation.* The recognized accreditation body must notify the laboratory of the laboratory's probation, and such notification must:

(1) Describe the grounds for the probation;

(2) Identify all deficiencies that the laboratory must correct for the recognized accreditation body to lift the probation; and either

(i) Inform the laboratory that it has a specific timeframe to take particular corrective actions with respect to the deficiencies identified by the recognized accreditation body, or

(ii) Require the laboratory to submit a plan to the recognized accreditation body for approval that identifies the appropriate corrective actions the laboratory will take to resolve the deficiencies identified by the recognized accreditation body, and identify appropriate timeframes for resolution; and

(g) *Consequences of probation or withdrawal of accreditation, in-whole or in-part.* If the recognized accreditation body withdraws the accreditation of a laboratory in-whole, the laboratory is immediately ineligible to conduct food testing under this subpart. If the recognized accreditation body withdraws the accreditation of a laboratory in-part, the laboratory is immediately ineligible to conduct food testing under this subpart with respect to only the specific method or methods for which accreditation was withdrawn. An accredited laboratory that is put on probation by an accreditation body is permitted to continue to conduct food testing under this subpart.

(h) *Appeals procedures.* A laboratory may appeal a decision by the recognized accreditation body to withdraw the accreditation (in-whole or in-part) of the laboratory, and the recognized accreditation body must consider the appeal in accordance with § 1.1118(b). In addition to meeting the requirements of § 1.1118(b) related to appeals, the recognized accreditation body must establish and implement written procedures to:

(1) Make the appeals procedures publicly available; and

(2) Use a competent person or persons, who may or may not be external to the recognized accreditation body, who are free from bias or prejudice and have not participated in the withdrawal decision, and are not the subordinate of a person who participated in the withdrawal decision, to review and decide appeals.

§ 1.1123 What reports and notifications must a recognized accreditation body submit to FDA?

(a) *General requirements.* All reports and notifications required by this section to be submitted to FDA must be submitted to FDA electronically and in English, and include:

(1) The name, street address, telephone number, and email address of the accreditation body associated with the report or notification, and the name of an appropriate point-of-contact for the accreditation body, and

(2) If there is a laboratory associated with the report or notification, the name, street address, telephone number, and email address of the laboratory associated with the report or notification, and the name of an appropriate point-of-contact for the laboratory.

(b) *Reporting results of recognized accreditation body internal audits.* A recognized accreditation body must submit to FDA a report of the results of the internal audit it is required to conduct pursuant to § 1.1118(b), including results of the audit of its compliance with the requirements of § 1.1118(c) and (d), conducted pursuant to § 1.1125, no later than 45 days after completing such internal audit, and the report must include:

(1) A description of the internal audit conducted;

(2) A description of any identified deficiencies;

(3) A description of any corrective actions taken and any corrective action the recognized accreditation body will take, including the timeline for such corrective actions; and

(4) A statement disclosing the extent to which the internal audit was conducted by personnel different from those who perform the activity or activities that were audited.

(c) *Immediate notification to FDA.* A recognized accreditation body must immediately, within 48 hours, notify FDA when the recognized accreditation body:

(1) Is aware of a change that would affect the recognition of such accreditation body, and the notification must include:

(i) A description of the change, and

(ii) If the change is one made by the recognized accreditation body, an explanation of the purpose of the change;

(2) Grants accreditation of a laboratory, and the notification must include:

(i) The scope of accreditation requested by the laboratory,

(ii) The scope of accreditation granted, and

(iii) The date on which accreditation was granted;

(3) Denies accreditation (in-whole or in-part) of a laboratory, and the notification must include:

(i) The scope of accreditation requested by the laboratory,

(ii) The scope of accreditation denied, and

(iii) The grounds for the denial;

(4) Receives notice that an accredited laboratory it accredited intends to relinquish its accreditation (in-whole or in-part), and the notification must include:

(i) The scope of accreditation to which the relinquishment applies, as applicable, and

(ii) The effective date of the relinquishment;

(5) Withdraws (in-whole or in-part) the accreditation of a laboratory; and the notification must include:

(i) The scope of accreditation to which the withdrawal applies, and

(ii) The grounds for the withdrawal;

(6) Puts an accredited laboratory on probation, and the notification must include:

(i) The grounds for the probation, and

(ii) Any date by which the recognized accreditation body has determined the accredited laboratory must take appropriate corrective action; and

(7) Knows that an accredited laboratory it accredits has committed fraud or submitted material false statements to FDA, and the notification must include:

(i) A description of the basis for the accreditation body's knowledge of the fraud or material false statements,

(ii) A description of the alleged fraud or material false statements, and

(iii) The actions taken by the recognized accreditation body with respect to such laboratory.

§ 1.1124 What records requirements must a recognized accreditation body meet?

(a) In addition to meeting the requirements of § 1.1118(b) related to records, a recognized accreditation body must maintain electronically, for 5 years after the date of creation of the records, records created while it is recognized demonstrating its compliance with this subpart, including records relating to:

(1) Applications for accreditation;

(2) Assessments, reassessments, and decisions to grant, renew, deny, withdraw, expand, or reduce the scope of an accreditation or place an accredited laboratory on probation;

(3) Appeals of probation and denials and withdrawals of accreditation, final decisions on such appeals, and the bases for such final decisions;

(4) Its oversight of accredited laboratories it accredited;

(5) Its oversight of its own performance, including all records related to internal audits, complaints, and corrective actions;

(6) Any reports or notifications required to be submitted to FDA under § 1.1123, including any supporting information; and

(7) Records of fee payments and reimbursement of direct costs.

(b) An accreditation body that has been recognized must make records it is required to maintain under paragraph (a) of this section available to FDA for inspection and copying promptly upon written request by an authorized FDA officer or employee at the place of business of the accreditation body or at a reasonably accessible location. If the records required by paragraph (a) of this section are requested by FDA electronically, the records must be submitted to FDA electronically not later than 10 business days after the date of the request. Additionally, if the requested records are maintained in a language other than English, the accreditation body must electronically submit an English translation within a reasonable time.

(c) A recognized accreditation body must not prevent or interfere with FDA's access to the records the accredited laboratories it accredits are required to maintain under § 1.1153.

§ 1.1125 What internal audit requirements must a recognized accreditation body meet?

As part of the internal audit a recognized accreditation body is required to conduct pursuant to § 1.1118(b), the recognized accreditation body must audit its compliance with the requirements of § 1.1118(c) and (d).

Procedures for Recognition of Accreditation Bodies

§ 1.1128 How does an accreditation body apply to FDA for recognition or renewal of recognition?

(a) *Applicant for recognition.* An accreditation body seeking recognition must submit an application to FDA demonstrating that it meets the eligibility requirements in § 1.1113.

(b) *Applicant for renewal of recognition.* An accreditation body seeking renewal of its recognition must submit a renewal application demonstrating that it continues to meet the requirements of this subpart.

(c) *Documentation of conformance with requirements.* The accreditation body must submit documentation of conformance with ISO/IEC 17011:2017 and separate documentation of ILAC MRA signatory status demonstrating competence to ISO/IEC 17011:2017, in meeting the requirements of § 1.1113(a) and (b) or § 1.1118(a) and (b), as applicable. The accreditation body also must submit documentation of its compliance with § 1.1113(c) and (d) or § 1.1118(c) and (d), as applicable.

(d) *Submission.* An accreditation body must submit recognition and renewal applications and any documents provided as part of the application process to FDA electronically, in English. The applicant must provide any translation and interpretation services needed by FDA during the processing of the application, including during any onsite assessments of the applicant by FDA.

(e) *Signature.* An accreditation body must sign the recognition and renewal applications in the manner designated by FDA. Recognition and renewal application must be signed by the applicant or by an individual authorized to act on behalf of the applicant for purposes of seeking recognition or renewal of recognition.

§ 1.1129 How will FDA review applications for recognition and applications for renewal of recognition?

(a) *Review of application for recognition or renewal of recognition.* FDA will examine an accreditation body's application for recognition or renewal of recognition for completeness and notify the applicant of any deficiencies. FDA will review an accreditation body's application for recognition or renewal of recognition on a first in, first out basis according to the date on which the completed application was submitted; however, FDA may prioritize the review of specific applications to meet program needs.

(b) *Evaluation of application for recognition or renewal of recognition.* FDA will evaluate any submitted application for recognition or renewal of recognition to determine whether the applicant meets the requirements for recognition. Such evaluation may include an onsite assessment of the accreditation body. FDA will notify the applicant, in writing, regarding whether the application has been approved or denied. FDA may make such notification electronically. If FDA does not reach a final decision on a renewal application before an accreditation body's recognition terminates by expiration, FDA may extend the existing term of recognition for a specified period of time or until FDA reaches a final decision on the renewal application.

(c) *Issuance of recognition.* FDA will notify the applicant that its application for recognition or renewal of recognition has been approved through issuance of recognition that will list any conditions associated with the recognition.

(d) *Duration of recognition.* FDA may grant recognition of an accreditation body for a period not to exceed 5 years

from the date of recognition, except under the circumstances described in paragraph (b) of this section.

(e) *Issuance of denial of application for recognition or renewal of recognition.* If FDA denies an applicant's application for recognition or renewal of recognition, FDA will notify the applicant, through an issuance of a notification of denial of recognition or denial of renewal of recognition. The notification of denial of recognition or denial of renewal of recognition will state the basis for such denial and describe the procedures for requesting reconsideration of the application under § 1.1171.

(f) *Notice of records custodian after denial of an application for renewal of recognition.* An applicant whose application for renewal of recognition was denied by FDA must notify FDA electronically, in English, within 10 business days of the date of issuance of a denial of a renewal application, of the name and contact information of the custodian who will maintain the records required by § 1.1124 and make them available to FDA as required by § 1.1124. The contact information for the custodian must include, at a minimum, an email address and the street address where the records required by § 1.1124 will be located.

(g) *FDA notice to accredited laboratories.* FDA will promptly issue a notice of the denial of the application for renewal of recognition of the accreditation body to all laboratories accredited by the accreditation body whose application for renewal of recognition was denied.

(h) *Public notice of denial of an application for renewal of recognition of an accreditation body.* FDA will provide public notice on the website described in § 1.1109 of the issuance of a denial of a renewal application and will include the date of the issuance of the denial of a renewal application.

§ 1.1130 How will FDA oversee recognized accreditation bodies?

(a) FDA will assess each recognized accreditation body to determine its compliance with the applicable requirements of this subpart. Such assessment will occur by at least 4 years after the date of recognition for a 5-year recognition period, or by no later than the mid-term point for a recognition period of less than 5 years. An FDA assessment of a recognized accreditation body may include review of records, an onsite assessment of the accreditation body, and onsite assessments of one or more accredited laboratories the recognized accreditation body accredits, with or without the recognized accreditation body present.

(b) FDA may conduct additional assessments of a recognized accreditation body at any time to determine the recognized accreditation body's compliance with the applicable requirements of this subpart.

§ 1.1131 When will FDA revoke the recognition of an accreditation body or put a recognized accreditation body on probation?

(a) *Grounds for revocation of recognition.* FDA will revoke the recognition of an accreditation body if it fails to meet the requirements of this subpart, or where FDA determines the accreditation body has committed fraud or submitted material false statements to FDA.

(b) *Issuance of revocation.* (1) FDA will notify the accreditation body that its recognition has been revoked through the issuance of a revocation that will state the grounds for revocation, the procedures for requesting a regulatory hearing under § 1.1173 on the revocation, and the procedures for requesting reinstatement of recognition under § 1.1133.

(2) Within 10 business days of the date of issuance of revocation, the accreditation body must notify FDA electronically, in English, of the name of the custodian who will maintain records and make them available to FDA as required by § 1.1124. The contact information for the custodian must provide, at a minimum, an email address and the street address where the records will be located.

(c) *Grounds for probation.* If FDA determines that a recognized accreditation body has demonstrated deficiencies in performing its functions that are less serious and more limited than those identified in paragraph (a) of this section, and it is reasonably likely that the accreditation body will be able to correct such deficiencies within a reasonable period of time, FDA may temporarily put the recognized accreditation body on probation and request that the accreditation body take appropriate corrective actions.

(d) *Length of probation.* FDA's probation of an accreditation body's recognition shall remain in effect until the accreditation body demonstrates to FDA's satisfaction that the accreditation body has successfully implemented appropriate corrective actions to address the deficiencies specified by FDA within the time period identified by FDA, or until FDA revokes the recognition of the accreditation body.

(e) *Notification of probation.* FDA will notify the accreditation body of its probation and such notification will:

(1) Describe the grounds for the probation;

(2) Identify all deficiencies that must be corrected for FDA to lift the probation and identify a specified period of time to take corrective actions to address the deficiencies specified by FDA.

(f) *Effect of revocation of recognition or probation on the accreditation body.* (1) An accreditation body that has had its recognition revoked by FDA may not accredit laboratories under this subpart or continue to oversee the laboratories it has previously accredited.

(2) A recognized accreditation body that is put on probation by FDA will be expected to continue to oversee laboratories that it has accredited under this subpart and is permitted to continue to accredit laboratories under § 1.1120 of this subpart.

(g) *FDA notice to the accredited laboratories.* FDA will issue a notice of the probation or revocation of recognition to all laboratories accredited by the recognized accreditation body that was put on probation or the accreditation body whose recognition was revoked.

(h) Public notice of probation or revocation of recognition. FDA will provide notice on the website described in § 1.1109 of the issuance of the probation or revocation of recognition of an accreditation body.

§ 1.1132 What must a recognized accreditation body do if it wants to voluntarily relinquish its recognition or does not want to renew its recognition?

(a) *Notice to FDA of intent to relinquish or not to renew recognition.* A recognized accreditation body must notify FDA electronically, in English, at least 60 days before voluntarily relinquishing its recognition or before allowing its recognition to expire without seeking renewal. The recognized accreditation body must provide the name and contact information of the custodian who will maintain the records required under § 1.1124 after the date of relinquishment or the date recognition expires, as applicable, and make them available to FDA as required by § 1.1124. The contact information for the custodian must include, at a minimum, an email address and the street address where the records required by § 1.1124 will be located.

(b) *Notice to accredited laboratories of intent to relinquish or not to renew recognition.* At least 60 days before voluntarily relinquishing its recognition

or before allowing its recognition to expire without seeking renewal, a recognized accreditation body must notify the laboratories it accredited of its intention to leave the program, specifying the date on which relinquishment or expiration will occur.

(c) *Public notice of voluntary relinquishment or expiration of recognition.* FDA will provide notice on the website described in § 1.1109 of the voluntary relinquishment or expiration of recognition of an accreditation body.

§ 1.1133 How does an accreditation body request reinstatement of recognition?

(a) *Application following revocation of recogniion.* An accreditation body that has had its recognition revoked by FDA may seek reinstatement by submitting a new application for recognition under § 1.1128. The accreditation body must also submit evidence to FDA with its application that the grounds for revocation have been resolved, including evidence addressing the cause(s) or condition(s) that were the grounds for revocation and must identify measures that have been implemented to help ensure that such cause(s) or condition(s) are unlikely to recur.

(b) *Application following relinquishment or expiration of recognition.* An accreditation body that previously relinquished its recognition or allowed its recognition to expire may seek recognition by submitting a new application for recognition under § 1.1128.

Accreditation of Laboratories

§ 1.1138 What requirements must a laboratory meet to become accredited by a recognized accreditation body?

(a) To become accredited by a recognized accreditation body, an accredited laboratory must:

(1) Demonstrate it is capable of conducting each method of food testing for which it seeks to be accredited, by:

(i) Submitting information to demonstrate appropriate verification or validation of the method(s), including the information required by § 1.1151(c)(2) and (d)(2), and a statement by the laboratory based on the verification or validation results of whether the laboratory is able to properly apply the method; and

(ii) Passing, or having passed within the past year, a proficiency test for the method, subject to the exception that if the laboratory determines there is no proficiency testing program available that addresses the method, or that proficiency testing for the method is otherwise impracticable, the accredited laboratory may instead subject, or have subjected in the past year, the method to an appropriate comparison program. The laboratory's determination must be reviewed by, and approved or denied (as appropriate) by, the recognized accreditation body from which the laboratory is seeking accreditation.

(2) Except as provided in paragraph (b) of this section, demonstrate it complies with ISO/IEC 17025:2017, ''General Requirements for the Competence of Testing and Calibration Laboratories,'' Third edition, November 2017. The Director of the Federal Register approves this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. The approved material is available for inspection at Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 301–827–6860, and is available from International Organization for Standardization (ISO), Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland; Telephone 41 22 749 01 11, *https://www.iso.org/home.html.* It is also available for inspection 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 *www.archives.gov/federal-register/cfr/ibr-locations.*

(b) For purposes of this program the laboratory is not required to satisfy the following provisions of ISO/IEC 17025:2017:

(1) That relate to the relationship between the laboratory and its customers, to the extent that such provisions establish obligations that conflict with the requirements of this subpart;

(2) In section 7: 7.3; or

(3) In section 7: 7.8.

(c) Demonstrate it is capable of meeting and operating in conformance with all of this subpart's additional requirements for accredited laboratories.

Requirements for Accredited Laboratories

§ 1.1146 What are the general requirements for accredited laboratories to remain accredited?

To remain accredited, the accredited laboratory must:

(a) Be capable of conducting the methods of analysis for the testing of food for which it is accredited;

(b) Maintain conformance with the provisions of ISO/IEC 17025:2017, ''General Requirements for the Competence of Testing and Calibration Laboratories,'' Third edition, November 2017. The Director of the Federal Register approves this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. The approved material is available for inspection at Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 301–827–6860, and is available from International Organization for Standardization (ISO), Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland; Telephone 41 22 749 01 11, *https://www.iso.org/home.html.* It is also available for inspection 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 *www.archives.gov/federal-register/cfr/ibr-locations.* This requirement is subject to the exceptions in § 1.1138(b); and

(c) Operate in conformance with the additional requirements of this subpart.

§ 1.1147 What impartiality and conflict of interest requirements must accredited laboratories meet?

(a) In addition to the requirements relating to impartiality and conflict of interest an accredited laboratory is required to meet under § 1.1146(b), the accredited laboratory must, subject to the exceptions in paragraph (b) of this section, prohibit the accredited laboratory's employees, contractors, and agents involved in food testing and related activities from accepting any money, gift, gratuity, or other item of value from the owner or consignee of the food that is being tested or will be tested by the accredited laboratory.

(b) The prohibited items of value specified in paragraph (a) of this section do not include:

(1) Payment of fees for food testing services;

(2) Reimbursement of direct costs associated with the food testing by the accredited laboratory; and

(3) With respect to accredited laboratories that are owned by the owner or consignee of the food that is tested or to be tested, payment of the officer's, employee's, contractor's, or agent's compensation in the normal course of business.

(c) The owner or consignee's payment to the accredited laboratory of fees for food testing services and/or reimbursement of direct costs associated with food testing must be independent of whether the test results indicate that food is or appears to be violative.

§ 1.1148 What quality assurance requirements must accredited laboratories meet?

In addition to the requirements relating to quality assurance an accredited laboratory is required to meet by § 1.1146(b), accredited labs must:

(a) Meet the following proficiency testing requirements:

(1) Accredited laboratories must participate in a proficiency testing program or programs provided by a competent proficiency testing organization, except as provided in paragraph (a)(2) of this section. The accredited laboratory must ensure such proficiency testing is conducted at least once per year for each method within the accredited laboratory's scope of accreditation.

(2) If the accredited laboratory determines there is no proficiency testing program available that addresses a particular method of analysis in the accredited laboratory's scope of accreditation, or that participating in a proficiency testing program for the particular method of analysis is otherwise impracticable, the accredited laboratory may subject that method of analysis to an appropriate comparison program. The determination must be reviewed, and approved or denied (as appropriate), by the recognized accreditation body that accredits the accredited laboratory.

(b) Ensure its procedures for monitoring the validity of the results of testing it conducts under this subpart include the use of reference materials or quality control samples with each batch of samples it tests under this subpart.

§ 1.1149 What oversight standards apply to sampling?

(a) Before analyzing a sample, the accredited laboratory must develop (if it collected the sample) or obtain (if another entity collected the sample):

(1) Written documentation of the sampler's applicable qualifications by training and experience. An accredited laboratory only needs to develop or obtain documentation of a sampler's qualifications the first time that individual collects a sample under this subpart, unless the accredited laboratory learns that the sampler's qualifications have significantly changed since the accredited laboratory last obtained documentation of the sampler's qualifications;

(2) A written sampling plan used to conduct the sampling. The written sampling plan must identify the sampler and must list factors that will be controlled to ensure the sampling does not impact the validity of the subsequent analytical testing, including controlling for the representational nature of the sample; and

(3) A written sample collection report for each sample collected. The written sample collection report must, at a minimum, include:

(i) The product code of the food product sampled (if product is being sampled) or the location of and a description of the environment (if environment is being sampled);

(ii) The date(s) of the sampling;

(iii) The size, identity, and quantity of the sample(s);

(iv) Documentation of sample collection procedures and any sample preparation techniques; and

(v) Documentation of the chain of custody of the sample(s), and of measures taken, to not impact the validity of the subsequent analytical testing, including controlling for the representational nature of the sample(s).

(b) If any of the requirements in paragraph (a) of this section are not met, FDA may consider the analysis of the sample to be invalid.

§ 1.1150 What requirements apply to analysis of samples by an accredited laboratory?

In addition to meeting the requirements of § 1.1146(b):

(a) The analysis must be conducted on either the sample(s) received from the sampler or, if appropriate, on a representative sample of the sample(s) received from the sampler.

(b) The analyst(s) that conducts the analysis must:

(1) Be qualified by appropriate education, training, and/or experience to conduct the analysis;

(2) Have appropriately demonstrated their ability to perform the method properly in the specific context of the food testing to be conducted; and

(3) Be in compliance with the conflict of interest requirements of §§ 1.1146(b) and 1.1147.

(c) The method used to conduct the food testing must meet the requirements of § 1.1151.

(d) The accredited laboratory must document the testing information and test results to the extent necessary to account for all information that is required to be included in a full analytical report (see § 1.1152(g)).

§ 1.1151 What requirements apply to the methods of analysis an accredited laboratory uses to conduct food testing under this subpart?

In addition to meeting the requirements of § 1.1146(b), an accredited laboratory must meet the following requirements:

(a) Analysis under this subpart must be conducted using a method of analysis that:

(1) Is fit for purpose;

(2) Is within the accredited laboratory's scope of accreditation;

(3) Has been appropriately validated for use in such food testing, in accordance with paragraph (c) of this section; and

(4) Has been appropriately verified by the accredited laboratory for use in such food testing, in accordance with paragraph (d) of this section.

(b) With respect to food testing conducted under:

(1) Section 1.1107(a)(1), if the Federal Food, Drug, and Cosmetic Act or implementing regulations prescribes a test method, that is the only appropriate method that may be conducted for such food testing;

(2) Section 1.1107(a)(2), if the food testing order prescribes a test method, that is the only appropriate method that may be conducted for such food testing.

(c)(1) An accredited laboratory must validate methods in accordance with the requirements of § 1.1146(b).

(2) An accredited laboratory performing validation of a method under this subpart must record the information required by the requirements of § 1.1146(b), and the supporting analytical data.

(d)(1) Before an accredited laboratory conducts food testing under this subpart using a method for a specific intended use for which the method has been validated, but for which the laboratory has not previously applied the method under this subpart, the accredited laboratory must have verified it can properly perform the method for the specific intended use.

(2) An accredited laboratory performing verification of a method under this subpart must record the method that is the subject of the verification, the intended purpose of the analysis, the results of the verification, the procedure used for the verification, supporting analytical data, and whether the accredited laboratory is able to properly perform the method.

(e) An accredited laboratory may submit a written request to FDA requesting FDA's permission to use a method or methods outside of its scope of accreditation for food testing. FDA may approve the request if both following conditions are satisfied:

(1) A new methodology or methodologies have been developed and validated but no reasonably available laboratory has been accredited to perform such methodology or methodologies, and

(2) The use of such method or methods is necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak.

§ 1.1152 What notifications, results, and reports must accredited laboratories submit to FDA?

(a) *General requirements.* (1) All notifications, results, reports, and

studies required to be submitted to FDA by accredited laboratories under this subpart must be submitted to FDA electronically and in English, and:

(i) Include the legal name and street address of the accredited laboratory, identify a point-of-contact for the accredited laboratory that FDA may contact with questions or comments regarding the notification, result, report, or study, and include the email address and telephone number of the point-of-contact;

(ii) Display an identification unique to the test results, report, notification, or study; and

(iii) Be true, accurate, unambiguous, and objective.

(2) The accredited laboratory that conducts the analysis of the sample under this subpart is responsible for the submission of all notifications, results, reports, and studies to FDA as required by this section.

(3) If the accredited laboratory that is responsible for the submission of same becomes aware that any aspect of the submitted material is inaccurate, the accredited laboratory must immediately inform FDA and submit a corrected version. Such corrections must meet the requirements for amendments to reports specified by ISO/IEC 17025:2017 section 7.8.8. ISO/IEC 17025:2017, ''General Requirements for the Competence of Testing and Calibration Laboratories,'' Third edition, November 2017. The Director of the Federal Register approves this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. The approved material is available for inspection at Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 301–827–6860, and is available from International Organization for Standardization (ISO), Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland; Telephone 41 22 749 01 11, *https://www.iso.org/home.html.* It is also available for inspection 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 *www.archives.gov/federal-register/cfr/ibr-locations.*

(4) Any opinions and interpretations in any notification, result, report, or study submitted to FDA under this subpart must meet the requirements in ISO/IEC 17025:2017 section 7.8.7 and any statements of conformity to a specification or standard in any notification, result, report, or study submitted to FDA under this subpart must meet the requirements of ISO/IEC 17025:2017 section 7.8.6.

(b) *Test results.* (1) The results of any and all tests conducted by an accredited laboratory under this subpart must be submitted directly to FDA.

(2) The accredited laboratory must submit the results of testing conducted under this subpart directly to FDA via the destination specified by the website described by § 1.1109, unless directed to use a different method of submission by FDA regarding testing conducted under § 1.1107(a)(2) or (3).

(3) The test results must be clear and identify the associated notifications, reports, and studies required to be submitted with the test results under this subpart.

(c) *Documentation required to be submitted with test results.* The following documentation must be submitted to FDA with each test result submitted to FDA under this subpart:

(1) All sampling plans and sample collection reports related to the food testing conducted, as developed or obtained by the accredited laboratory in accordance with § 1.1149;

(2) Written documentation of the sampler's qualifications, if § 1.1149(a)(1) requires the accredited laboratory to obtain such documentation;

(3) The full analytical report required by paragraph (g) of this section, documenting the analysis related to the food testing, except that if the accredited laboratory is permitted in accordance with paragraph (d) of this section to submit abridged analytical reports, the accredited laboratory may instead submit an abridged analytical report, which must contain the information required by paragraph (f) of this section;

(4) For any validation studies required by § 1.1151(c)(1), the documentation required by § 1.1151(c)(2), except when the circumstances of paragraph (c)(6) of this section apply with respect to the validation study.

(5) For any verification studies required by § 1.1151(d)(1), the documentation required by § 1.1151(d)(2), except when the circumstances of paragraph (c)(6) of this section apply with respect to the verification study.

(6) Paragraphs (c)(4) and (5) of this section do not require the accredited laboratory to submit the validation or verification study to FDA if the accredited laboratory submitted the validation or verification study to its accreditation body as required by § 1.1138(a)(1)(i). If the accredited laboratory submitted the validation or verification study to its accreditation body as required by § 1.1138(a)(1)(i), the accredited laboratory must instead submit to FDA, in lieu of the validation or verification study, a statement that the validation or verification study has been submitted to its recognized accreditation body in accordance with § 1.1138(a)(1)(i), and the accredited laboratory must identify the method, analyte, and matrix that were the subject of the validation or verification study;

(7) A certification from one or more members of the accredited laboratory's management certifying that the test results, notifications, reports, and studies are true and accurate; and that the documentation includes the results of all tests conducted under this subpart. The certification must include the name, title, and signature of the certifier(s).

(d) *Permission to submit abridged analytical reports.* (1) Accredited laboratories that are not disqualified under paragraphs (d)(6)(i) and (d)(7) of this section or on probation are permitted to submit to FDA on an ongoing basis abridged analytical reports relating to a specific major food testing discipline(s) that is represented in the reports described in paragraph (d)(1)(ii) of this section, after FDA has given notice that the following conditions are fulfilled:

(i) The accredited laboratory submits 10 consecutive full analytical reports to FDA under this subpart;

(ii) The consecutive full analytical reports include at least one full analytical report relating to each major food testing discipline for which the accredited laboratory seeks to submit abridged analytical reports;

(iii) None of the consecutive full analytical reports demonstrate any material substantive shortcoming in the food testing; and

(iv) The consecutive full analytical reports do not contain repeated administrative deficiencies.

(2)(i) Accredited laboratories that fail to satisfy the condition in paragraph (d)(1)(iii) of this section are subject to the disqualification period described in paragraph (d)(6)(i) of this section.

(ii) Accredited laboratories that fail to satisfy the condition in paragraph (d)(1)(iv) of this section have a second attempt to satisfy the conditions in paragraphs (d)(1)(i) to (iv) of this section with 10 subsequent consecutive full analytic reports. If one of those subsequent consecutive full analytical reports demonstrate any material substantive shortcoming in the food testing, or the subsequent consecutive full analytical reports contain repeated administrative deficiencies, the accredited laboratory is subject to the disqualification period described in paragraph (d)(6)(i) of this section.

(3) Accredited laboratories that are not on probation and are currently permitted to submit abridged analytical reports for at least one major food testing discipline under this paragraph are permitted to submit to FDA on an ongoing basis abridged analytical reports relating to any additional major food testing disciplines that were not represented in the reports described in paragraph (d)(1)(ii) of this section, after FDA has given notice that the following conditions are fulfilled:

(i) The accredited laboratory submits to FDA at least one full analytical report for each additional major food testing discipline for which the accredited laboratory seeks to submit abridged analytical reports;

(ii) None of the full analytical reports for each additional major food testing discipline demonstrate any material substantive shortcoming in the food testing; and

(iii) None of the full analytical reports for each additional major food testing discipline contain repeated administrative deficiencies.

(4)(i) Accredited laboratories that fail to satisfy the condition in paragraph (d)(3)(ii) of this section for an additional major food testing discipline(s) are subject to the disqualification period described in paragraph (d)(6)(ii) of this section for such additional major food testing discipline(s).

(ii) Accredited laboratories that fail to satisfy the condition in paragraph (d)(3)(iii) of this section for an additional major food testing discipline(s) have a second attempt to satisfy the conditions in paragraphs (d)(3)(i) to (iii) of this section with at least one full analytic report for each additional major food testing discipline for which the accredited laboratory is seeking to submit abridged analytical reports. If that subsequent full analytical report(s) demonstrates any material substantive shortcoming in the food testing, or the subsequent full analytical report(s) contains repeated administrative deficiencies, the accredited laboratory is subject to the disqualification period described in paragraph (d)(6)(ii) of this section for the major food testing discipline that was the subject of the full analytical report containing the shortcoming or deficiencies.

(5) If one or more test results, notifications, reports, and/or studies relating to a specific major food testing discipline submitted to FDA under this subpart by an accredited laboratory that is permitted to submit abridged analytical reports for that major food testing discipline demonstrates any material substantive shortcoming in the related food testing or demonstrates repeated administrative deficiencies, the accredited laboratory is disqualified to submit abridged reports for that specific major food testing discipline in accordance with either paragraph (d)(6)(ii) of this section (if the accredited laboratory is permitted to submit abridged analytical reports for another discipline) or paragraph (d)(6)(i) of this section (if the accredited laboratory is not permitted to submit abridged analytical reports for any another discipline).

(6)(i) The period of disqualification is either 2 years or until the accredited laboratory submits 20 more full analytical reports to FDA under this subpart, whichever period of time is longer, after which time the accredited laboratory may request permission under paragraph (d)(7) of this section to fulfill the eligibility conditions under paragraph (d)(1) of this section.

(ii) The period of disqualification is either 2 years or until the accredited laboratory submits two more full analytical reports to FDA under this subpart, whichever period of time is longer, after which time the accredited laboratory may request permission under paragraph (d)(7) of this section to fulfill the eligibility conditions under paragraph (d)(3) of this section.

(iii) Whenever, during the period of disqualification described under paragraph (d)(6)(i) or (ii) of this section, a full analytical report submitted by an accredited laboratory demonstrates any material substantive shortcoming in the food testing, that accredited laboratory's disqualification period is extended by 6 months.

(iv) Whenever, during the period of disqualification described under paragraph (d)(6)(i) or (ii) of this section, the full analytical reports submitted by an accredited laboratory contain repeated administrative deficiencies, that accredited laboratory's disqualification period is extended by 2 months.

(7) An accredited laboratory that has fulfilled the conditions of paragraph (d)(6)(i) or (ii) of this section, as applicable, and that is not on probation, may submit a request to FDA via the destination specified by the website described by § 1.1109 to attempt to fulfill the conditions as described in paragraphs (d)(1) and (3) of this section, as applicable. FDA will consider permitting the accredited laboratory to again try and fulfill the conditions of paragraph (d)(1) or (3) of this section, as applicable. If FDA grants permission and upon fulfillment of those conditions, FDA will provide notice that the accredited laboratory is permitted to submit to FDA on an ongoing basis abridged analytical reports relating to the disciplines for which the conditions are fulfilled.

(e) *Exceptions to permission to submit abridged analytical reports.* (1) Occasionally, for the purposes of auditing abridged analytical reports and otherwise protecting the public health and the integrity of this food testing program, FDA will require that an accredited laboratory that is permitted to submit abridged analytical reports additionally submit to FDA the full analytical report within 48 hours of FDA's notice.

(2) FDA may require an accredited laboratory that is permitted to submit abridged analytical reports under this subpart to submit full analytical reports if such analytical reports relate to an FDA investigation or FDA enforcement proceeding.

(f) *Abridged analytical report contents.* Abridged analytical reports must contain:

(1) All information described by ISO/IEC 17025:2017 sections 7.8.2.1(a) through (p) and 7.8.3.1(a) through (d). ISO/IEC 17025:2017, ''General Requirements for the Competence of Testing and Calibration Laboratories,'' Third edition, November 2017. The Director of the Federal Register approves this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. The approved material is available for inspection at Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 301–827–6860, and is available from International Organization for Standardization (ISO), Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland; Telephone 41 22 749 01 11, *https://www.iso.org/home.html.* It is also available for inspection 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 *www.archives.gov/federal-register/cfr/ibr-locations;* and

(2) The justification for any modification or deviation to the method(s) of analysis used and documentation of the accredited laboratory's authorization for the modification or deviation.

(g) *Full analytical report contents.* Full analytical reports must contain:

(1) All information described by paragraphs (f)(1) and (2) of this section;

(2) Documentation of references for the method or methods of analysis used;

(3) Identification of the analyst or analysts who conducted each analytical step, validation step (if applicable), and verification step (if applicable),

including the analyst's or analysts' legal name and signature, and the date each analytical step, validation step (if applicable), and verification step (if applicable) was performed;

(4) Calculations, presented in a legible and logical manner;

(5) As applicable, references to chromatograms; charts; graphs; observations; photographs of thin layer chromatographic plates; and spectra. References must be in color when appropriate and made in a clear order;

(6) Identification of the source and purity of reference standards used, and, as applicable: Certified reference materials, certified reference cultures traceable to a nationally or internationally recognized type culture collection (including concentration, units preparation, and storage conditions), and reference standard preparation information (including who prepared the reference standard, date of preparation, expiration date, chemical balance, and solvent used);

(7) A copy of the label from any immediate container sampled and any additional labeling needed to evaluate the product;

(8) All original compilations of raw data secured in the course of the analysis, including discarded, unused or re-worked data, with the justification for discarding or re-working such data, corresponding supporting data, and quality control results all identified with unique sample identification, date and time, associated with the test;

(9) Any other relevant additional supporting information such as the storage location of analyzed samples, appropriate attachments such as instrument printouts, computer generated charts and data sheets, and photocopies or original labels for the product analyzed;

(10) Identification of any software used;

(11) Any certificate or certificates of analysis for standards and software; and

(12) The following information about the qualifications of the analyst or analysts who were involved in the analysis conducted under this subpart, if the accredited laboratory has not previously submitted documentation of the analyst's qualifications to FDA or the analyst's qualifications have significantly changed since the accredited laboratory last submitted documentation of the analyst's qualifications to FDA:

(i) The analyst's curriculum vitae;

(ii) Training records with regards to methods that the analyst is qualified to perform, including the dates of such training and the name of the trainer or training provider;

(iii) Any other documentation of the analyst's ability to perform the method properly in the context of the food testing to be conducted, pursuant to § 1.1150(b); and

(iv) Individual proficiency test worksheets relevant to the analysis being performed.

(h) *Additional information about non-standard methods.* If the accredited laboratory conducts the analysis using a method that is not published in a reputable international or national standard or that is otherwise not publicly and readily available, upon request by FDA the accredited laboratory must submit documentation of the method to FDA.

(i) *Advance notice of sampling.* (1) If FDA determines that the sampling conducted by a sampler may materially differ from the sampling documented in the associated sampling plan or sample collection report, or if FDA determines that the sampling may have been otherwise improper, FDA may require the accredited laboratory that analyzed the associated sample(s), and other accredited laboratories that have analyzed samples collected by the sampler previously, to request and receive from the sampler, and submit or require the sampler to submit, an advance notice of sampling to FDA 48 hours before each of the next 10 occasions that the sampler will collect a sample that the accredited laboratory will analyze under this subpart.

(2) FDA may, as appropriate:

(i) Specify the type of food product or environment that requires advance notice of sampling under this subpart,

(ii) Determine that an amount of time other than 48 hours in advance is required, to a minimum of 24 hours and up to 7 business days in advance, and

(iii) Determine that a number of occasions other than 10 are required, to a minimum of 1 occasion and up to a maximum of 20 occasions.

(iv) Notify affected accredited laboratories that submission of additional notices of sampling are not required.

(3) The advance notice of sampling must contain:

(i) A unique identification code for the advance notice of sampling;

(ii) The name of the accredited laboratory that will conduct analysis of the sample;

(iii) The name and street address of the sampler that will conduct the sampling;

(iv) A primary contact (name and phone number) for the sampler;

(v) The reason(s) why the food product or environment will be sampled;

(vi) The location of the food product or environment that will be sampled, including sufficient information to identify the food product or environment to be sampled;

(vii) As applicable, the U.S. Customs and Border Protection entry and line number(s) and the FDA product code(s) of the food; and

(viii) The date and approximate time the sampling will begin.

(j) *Immediate notification of significant changes.* When any changes occur that affect the accreditation of the accredited laboratory, the accredited laboratory must immediately, within 48 hours, send FDA and the accreditation body that accredited it notice of such changes, a detailed description of such changes, and an explanation of how such changes affect the accreditation of the accredited laboratory. Accredited laboratories are not required to notify FDA of changes that recognized accreditation bodies must provide notification of under § 1.1123(c).

(k) *Consequence of omission.* If FDA does not receive all information required to be submitted to FDA by paragraphs (a) through (j) of this section, FDA may consider the related food testing to be invalid.

§ 1.1153 What other records requirements must an accredited laboratory meet?

In addition to meeting the requirements of § 1.1146(b) related to records, laboratories that have been accredited must meet the following requirements:

(a) Maintain electronically, for 5 years after the date of creation, records created and received while they are accredited that relate to compliance with this subpart, including:

(1) Documents related to the accredited laboratory's grant (and, if applicable, expansions and reductions) of accreditation from its recognized accreditation body;

(2) Documentation of food testing the accredited laboratory conducted under this subpart, in accordance with § 1.1150(d);

(3) All documents that the accredited laboratory was required to submit to FDA under § 1.1152, and associated correspondence by the accredited laboratory (and its officers, employees, and other agents) with the owner or consignee (and its officer, employees, and other agents) of the tested food product or environment;

(4) All requests for food testing from an owner or consignee that would be conducted under this subpart;

(5) Documentation of any internal investigations, internal audits, and corrective actions taken to address any

problems or deficiencies related to activities under this subpart;

(6) Any and all documentation related to probation or withdrawal from accreditation under this subpart; and

(7) Documentation of changes to its management system or food testing activities that may affect its compliance with this subpart.

(b) Within 30 days of the receipt of proficiency testing results, submit the results:

(1) To the recognized accreditation body that accredits the accredited laboratory; and

(2) If the accredited laboratory failed the proficiency test, to FDA, via the destination specified by the website described by § 1.1109.

(c) Make the records required by paragraphs (a) and (b) of this section available for inspection and copying upon written request of an authorized officer or employee of FDA. The authorized officer or employee of FDA may request that the laboratory that has been accredited submit such records to FDA electronically or that the laboratory make such records promptly available at the physical location of the laboratory or at another reasonably accessible location. If the authorized officer or employee of FDA requests the records be submitted electronically, the records must be submitted electronically not later than 10 business days after the date of the request, except that records related to the immediate notification provision in § 1.1152(j) must be submitted within 48 hours. Additionally, if the authorized FDA officer or employee requests records that are maintained in a language other than English, the laboratory that has been accredited must electronically submit an English translation of the records to FDA within a reasonable time.

(d) Ensure that significant amendments to records described by paragraphs (a) and (b) of this section can be tracked to previous and original versions. If such a significant amendment is made, both the original document and amended document must be maintained by the laboratory that has been accredited during the time period that the amended document must be maintained under this subpart. The laboratory must also document the date of amendment, the personnel responsible for the amendment, and a conspicuous indication on the original document stating that the document has been altered and a more recent version of the document exists.

Procedures for Accreditation of Laboratories

§ 1.1158 How does a laboratory apply for accreditation or modification of its scope of accreditation by a recognized accreditation body?

(a) *Submission of application for accreditation to a recognized accreditation body.* A laboratory seeking accreditation must submit its application for accreditation to a recognized accreditation body identified on the website described in § 1.1109. The recognized accreditation body will review and assess the application in accordance with the requirements of this subpart. If the laboratory seeking accreditation had its accreditation (in-whole or in-part) withdrawn by a recognized accreditation body or revoked by FDA the previous time it was accredited under this subpart, the laboratory must meet the additional requirements specified by § 1.1165.

(b) *Documentation of conformance with ISO/IEC 17025:2017.* The laboratory may use documentation of conformance with ISO/IEC 17025:2017, as applicable and supplemented as necessary, in meeting the applicable requirements of this subpart.

(c) *Duration of accreditation.* If an accredited laboratory maintains compliance with all requirements of this subpart including maintaining accreditation to ISO/IEC 17025:2017, the laboratory's accreditation does not end until withdrawn, revoked, or relinquished under this subpart.

§ 1.1159 How will FDA oversee accredited laboratories?

(a) FDA may assess accredited laboratories at any time to determine whether the accredited laboratory continues to comply with the applicable requirements of this subpart and whether there are deficiencies in the performance of the accredited laboratory that, if not corrected, would warrant probation or revocation of its accreditation under § 1.1161.

(b) In evaluating the performance of an accredited laboratory under paragraph (a) of this section, FDA may review any of the following:

(1) Records the accredited laboratory is required to maintain under this subpart;

(2) Records the accreditation body that accredited the accredited laboratory is required to maintain under this subpart;

(3) Information obtained by FDA during an onsite assessment by FDA of the accredited laboratory conducted pursuant to paragraph (c) of this section;

(4) Information obtained by FDA during an assessment of the recognized accreditation body that accredited the laboratory; and

(5) Any other information obtained by FDA, including during FDA's inspections or investigations of one or more owners or consignees of food subject to food testing under this subpart.

(c) FDA may conduct an onsite assessment of an accredited laboratory at any reasonable time, with or without a recognized accreditation body (or its officers, employees, and other agents) present, to assess an accredited laboratory.

(d) FDA will report any of its observations and findings of its assessment to the accredited laboratory's recognized accreditation body.

§ 1.1160 How will FDA review submitted test results and analytical reports?

(a) If FDA finds that any test result, analytical report, related documents, or the associated analysis contains deficiencies or otherwise indicates that any aspect of the food testing is not being conducted in compliance with this subpart, FDA:

(1) May consider the analysis to be invalid; and/or

(2) Will notify the accredited laboratory that appears to be responsible for the deficiency and may also notify the owner or consignee of the food of the deficiency. When we notify the accredited laboratory that appears to be responsible for the deficiency, the accredited laboratory must respond, in writing, to FDA regarding the deficiency within 30 days or an agreed-upon timeframe, including a statement with respect to how the accredited laboratory intends to address the deficiency, and/or a statement describing the extent to which the laboratory has addressed the deficiency.

(b) FDA may report FDA's determinations of any deficiencies resulting from its review of any test results, reports, and related documents under this subpart to the recognized accreditation body that accredits the accredited laboratory.

(c) If the deficiency in the test result, analytical report, and/or associated analysis demonstrates a material substantive shortcoming in the related food testing or demonstrates repeated administrative deficiencies, FDA will also consider whether disqualification from being eligible for permission to submit abridged analytic reports under § 1.1152(d), and/or other action under this subpart, is appropriate.

(d) Nothing in this subpart shall be construed to limit the ability of FDA to review and act upon information

received about food testing, including determining the sufficiency of such information and testing.

§ 1.1161 When will FDA put an accredited laboratory on probation or revoke the accreditation of a laboratory?

(a) *Grounds for revocation of accreditation.* FDA may revoke the accreditation (in-whole or in-part) of an accredited laboratory to conduct food testing under this subpart for good cause, which may include any of the following reasons:

(1) Demonstrated bias or lack of objectivity when conducting food testing under this subpart where the laboratory's recognized accreditation body fails to withdraw accreditation of the laboratory.

(2) Performance that calls into question the validity or reliability of its food testing under this subpart where the laboratory's recognized accreditation body fails to withdraw accreditation of the laboratory.

(3) Other failure to substantially comply with this subpart where the laboratory's recognized accreditation body fails to withdraw accreditation of the laboratory.

(b) *Grounds for probation.* If FDA determines that an accredited laboratory has demonstrated deficiencies in performing its functions that are less serious and more limited than those identified in paragraph (a) of this section, and it is reasonably likely that the accredited laboratory will be able to correct such deficiencies within a specified period of time, FDA may temporarily put the accredited laboratory on probation and request that the laboratory take appropriate corrective actions.

(c) *Revocation in-part.* When there are grounds for revocation of accreditation of a laboratory, but the deficiencies affect only certain methods within the accredited laboratory's scope of accreditation, FDA may revoke the accredited laboratory's accreditation only for those affected methods.

(d) *Length of probation.* FDA's probation of a laboratory's accreditation shall remain in effect until the laboratory demonstrates to FDA's satisfaction that the laboratory has successfully implemented appropriate corrective actions, or until FDA determines that revocation of accreditation is warranted.

(e) *Notice to the accredited laboratory of revocation of accreditation.* FDA will notify a laboratory and its accreditation body of the revocation of its accreditation through issuance of a revocation notice that will state:

(1) The grounds for revocation;

(2) Whether the revocation of accreditation is in-whole or in-part, and if it is in-part, to which method or methods it applies;

(3) The procedures for requesting a regulatory hearing under § 1.1173 on the revocation; and

(4) The procedures for requesting reinstatement of accreditation under § 1.1165.

(f) *Notification of probation.* FDA will notify a laboratory and its accreditation body of the probation and such notification will:

(1) Describe the grounds for the probation; and

(2) Identify all deficiencies that must be corrected for FDA to lift the probation; and will either:

(i) Inform the laboratory that the laboratory has a specified time period to take corrective actions specified by FDA; or

(ii) Request that the laboratory submit a corrective action plan to FDA for FDA's approval that identifies the corrective actions it will take to address deficiencies identified in the notice and identify timeframes for completion.

(g) *Revocation following probation.* FDA may revoke (in-whole or in-part) the accreditation of a laboratory that has been put on probation if FDA determines that the laboratory is not implementing appropriate corrective actions.

(h) *Public notice of probation or revocation of accreditation.* FDA will provide notice on the website described in § 1.1109 of probation or revocation of accreditation of a laboratory.

§ 1.1162 What are the consequences if FDA puts an accredited laboratory on probation or revokes the accreditation of a laboratory?

(a) If FDA revokes the accreditation of a laboratory in-whole, the laboratory is immediately ineligible to conduct food testing under this subpart. If FDA revokes the accreditation of a laboratory in-part, the laboratory is immediately ineligible to use the methods that are subject to the revocation to conduct food testing under this subpart. An accredited laboratory that is put on probation by FDA is permitted to continue to conduct food testing under this subpart.

(b) With respect to food testing conducted by the laboratory prior to the revocation of accreditation, FDA may refuse to consider specific food testing results and associated reports of food testing conducted under this subpart by the laboratory if the basis for the revocation of accreditation of the laboratory indicates that the specific food testing conducted by the laboratory may not be reliable.

(c) Within 10 business days of the date of issuance of revocation, the laboratory must notify FDA electronically, in English, of the name of the custodian who will maintain the records required by § 1.1153, and provide contact information for the custodian, which will at least include an email address, and the street address where the records will be located.

(d) Within 10 business days of the date of issuance of probation or revocation, the laboratory must notify any owners or consignees that it is conducting food testing on behalf of under this subpart that it is on probation or its accreditation has been revoked.

§ 1.1163 What if a laboratory wants to voluntarily relinquish its accreditation?

(a) *Notice to FDA and the recognized accreditation body of intent to relinquish.* An accredited laboratory must notify FDA electronically, in English, and must notify its recognized accreditation body at least 60 days before voluntarily relinquishing accreditation (in-whole or in-part). The notice must include the date on which relinquishment will occur. If the relinquishment is of the laboratory's accreditation in-whole, the notification must also include the name and contact information of the custodian who will maintain the records required under § 1.1153 after the date of relinquishment, and the laboratory must make such records available to FDA as required by § 1.1153. The contact information for the custodian must include, at a minimum, an email address and the street address where the records required by § 1.1153 will be located.

(b) *Public notice of voluntary relinquishment of accreditation.* FDA will provide notice on the website described in § 1.1109 of the voluntary relinquishment of accreditation of a laboratory.

§ 1.1164 What is the effect on accredited laboratories if their accreditation body voluntarily or involuntarily loses its recognition?

(a) If an accreditation body has its recognition revoked, relinquishes its recognition, allows its recognition to expire, or has its application for renewal of recognition denied, the laboratory accredited by the accreditation body must take the following actions (subject to the exception in paragraph (b) of this section):

(1) No later than 30 days after FDA issues the notice to the accredited laboratory under § 1.1129, § 1.1130, or § 1.1131 that the accreditation body that accredits the laboratory has had its

recognition revoked, has relinquished its recognition, has allowed its recognition to expire, or has had its application for renewal of recognition denied, the accredited laboratory submits to FDA documentation of the accredited laboratory's most recent internal audit, which all accredited laboratories are required to maintain under § 1.1153(a)(5), documentation showing compliance with the conflict of interest requirements in § 1.1147, and documentation of the most recent proficiency test for each test method for which the laboratory is accredited under this subpart, to show compliance with § 1.1138(a)(1)(ii); and

(2) No later than 1 year after FDA issues the applicable notice under § 1.1129, § 1.1130, or § 1.1131 to the accredited laboratory, the laboratory becomes accredited under this subpart by a recognized accreditation body.

(b) The accredited laboratory does not have to comply with paragraph (a) of this section if, no later than 15 days after FDA issues the applicable notice to the accredited laboratory under § 1.1129, § 1.1130, or § 1.1131, the accredited laboratory initiates relinquishment of its accreditation in-whole under § 1.1163, with the relinquishment to occur within no more than 90 days.

§ 1.1165 How does a laboratory request reinstatement of accreditation?

(a) *Application following withdrawal of accreditation by a recognized accreditation body or revocation of accreditation by FDA.* A laboratory that had its accreditation (in-whole or in-part) withdrawn by a recognized accreditation body or revoked by FDA may seek reinstatement of accreditation by submitting a new application for accreditation (in-whole or in-part, as applicable) to a recognized accreditation body under § 1.1158, and the laboratory must also:

(1) Notify FDA, before it submits the new application for accreditation to the recognized accreditation body, that the laboratory will be submitting a new application for accreditation to the recognized accreditation body, including in the notification the legal name of the laboratory, valid contact information for the laboratory, the legal name of the recognized accreditation body the laboratory will be submitting the application to, and the date that the laboratory expects to submit the new application for accreditation; and

(2) Demonstrate, to the satisfaction of the recognized accreditation body it is submitting the new application to, that the grounds for the withdrawal of accreditation have been resolved and that the laboratory has implemented measures to prevent such grounds from recurring.

(b) *Application following voluntary relinquishment of accreditation.* A laboratory that voluntarily relinquished its accreditation (in-whole or in-part), pursuant to § 1.1163, may seek reaccreditation by submitting a new application for accreditation to a recognized accreditation body under § 1.1158.

Requesting FDA Reconsideration, FDA Internal Review, or Regulatory Hearings of FDA Decisions Under This Subpart

§ 1.1171 How does an accreditation body request reconsideration by FDA of a decision to deny its application for recognition, renewal, or reinstatement?

(a) *Timing of request.* An accreditation body may seek reconsideration of FDA's decision to deny its application for recognition, renewal of recognition, or reinstatement of recognition no later than 10 business days after the date of the issuance of such denial.

(b) *Submission of request.* The request to reconsider an application under paragraph (a) of this section must be signed by the accreditation body, as appropriate, or by an individual authorized to act on its behalf. The accreditation body must submit the request to FDA electronically, in English, and in accordance with the procedures described in the notice of denial.

(c) *Notification of FDA's decision.* After completing its review and evaluation of the request for reconsideration and any supporting information submitted pursuant to paragraph (b) of this section, FDA will notify the accreditation body of its decision to grant recognition upon reconsideration or deny recognition upon reconsideration.

§ 1.1173 How does an accreditation body or laboratory request a regulatory hearing on FDA's decision to revoke the recognized accreditation body's recognition or revoke the accredited laboratory's accreditation?

(a) *Request for hearing.* No later than 10 business days after the date FDA issued a revocation of recognition of an accreditation body pursuant to § 1.1131 or revocation of accreditation of a laboratory pursuant to § 1.1161, the accreditation body, laboratory, or an individual authorized to act on the accreditation body's or laboratory's behalf, may submit a request for a regulatory hearing, conducted pursuant to part 16 of this chapter, on the revocation. The notice of revocation issued under § 1.1131 or § 1.1161, as applicable, will contain all the elements required by § 16.22(a) of this chapter and will thereby constitute the notice of an opportunity for hearing under part 16 of this chapter.

(b) *Submission of request for regulatory hearing.* The request for a regulatory hearing under this subpart must be submitted with a written appeal that responds to the bases for the FDA decision described in the written notice of revocation, together with any supporting information upon which the requestor is relying. The request, appeal, and supporting information must be submitted to FDA electronically, in English, in accordance with the procedures described in the notice of revocation.

(c) *Effect of submitting a request for a regulatory hearing on an FDA decision.* The submission of a request for a regulatory hearing under this subpart will not operate to delay or stay the effect of a decision by FDA to revoke recognition of an accreditation body or revoke the accreditation of laboratory unless FDA determines that delay or a stay is in the public interest.

(d) *Presiding officer.* The presiding officer for a regulatory hearing under this subpart will be designated after a request for a regulatory hearing is submitted to FDA.

(e) *Denial of a request for regulatory hearing.* The presiding officer may deny a request for regulatory hearing under this subpart pursuant to § 16.26(a) of this chapter when no genuine or substantial issue of fact has been raised.

(f) *Conduct of regulatory hearing.* (1) If the presiding officer grants a request for a regulatory hearing, the hearing will be held within 10 business days after the date the request was filed or, if applicable, within a timeframe agreed upon in writing by the accreditation body, laboratory, and the presiding officer and FDA.

(2) The presiding officer must conduct the hearing in accordance with part 16 of this chapter, except that, pursuant to § 16.5(b) of this chapter, the procedures for a regulatory hearing apply only to the extent that such procedures are supplementary and do not conflict with the procedures specified for regulatory hearings under this subpart. Accordingly, the following requirements of part 16 of this chapter are inapplicable to regulatory hearings conducted under this subpart: The requirements of § 16.22 (Initiation of a regulatory hearing); § 16.24(e) (timing) and (f) (contents of notice); § 16.40 (Commissioner); § 16.60(a) (public process); § 16.95(b) (administrative decision and record for decision); and

§ 16.119 (Reconsideration and stay of action).

(3) A decision by the presiding officer to affirm the revocation of recognition or revocation of accreditation is considered a final agency action under 5 U.S.C. 702.

§ 1.1174 How does an owner or consignee request a regulatory hearing on a food testing order?

(a) *Request for hearing.* No later than 24 hours after the time at which FDA issued the food testing order, an owner or consignee may submit a request for a regulatory hearing, conducted pursuant to part 16 of this chapter, on the food testing order. The food testing order will contain all of the elements required by § 16.22 of this chapter and will thereby constitute the notice of an opportunity for hearing under part 16 of this chapter.

(b) *Submission of request for regulatory hearing.* The request for a regulatory hearing must be submitted with a written appeal that responds to the bases, as appropriate, for FDA's determinations described in the food testing order, together with any supporting information upon which the requestor is relying. The request, appeal, and supporting information must be submitted in English to the destination specified in such notice and in accordance with the procedures described therein. The request, appeal, and supporting information may be submitted electronically.

(c) *Presiding officer.* The presiding officer for a regulatory hearing under this subpart will be designated after a request for a regulatory hearing is submitted to FDA.

(d) *Denial of a request for regulatory hearing.* The presiding officer may deny a request for regulatory hearing under this subpart pursuant to § 16.26(a) of this chapter.

(e) *Conduct of regulatory hearing.* (1) If the presiding officer grants a request for a regulatory hearing, such hearing will be held within 2 business days after the date the request was filed or, if applicable, within a timeframe agreed upon in writing by the requestor and the presiding officer and FDA.

(2) The presiding officer may require that a hearing conducted under this subpart be completed within 1 business day, as appropriate.

(3) The presiding officer must conduct the hearing in accordance with part 16 of this chapter, except that, pursuant to § 16.5(b) of this chapter, the procedures for a regulatory hearing described in part 16 of this chapter apply only to the extent that such procedures are supplementary and not in conflict with the procedures specified for the conduct of regulatory hearings under this subpart. Accordingly, the following requirements of part 16 of this chapter are inapplicable to regulatory hearings conducted under this subpart: § 16.22 (Initiation of a regulatory hearing); § 16.24(e) (timing) and (f) (contents of notice); § 16.40 (Commissioner); § 16.60(a) (public process); § 16.95(b) (administrative decision and record for decision); and § 16.119 (Reconsideration and stay of action).

(4) A decision by the presiding officer to affirm the food testing order is considered a final agency action under 5 U.S.C. 702.

Electronic Records and Public Disclosure Requirements Under This Subpart

§ 1.1199 Are electronic records created under this subpart subject to the electronic records requirements of part 11 of this chapter?

Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

§ 1.1200 Are the records obtained by FDA under this subpart subject to public disclosure?

Records obtained by FDA under this subpart are subject to the disclosure requirements under part 20 of this chapter.

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

■ 4. The authority citation for part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

■ 5. In § 11.1, add paragraph (p) to read as follows:

§ 11.1 Scope.

* * * * *

(p) This part does not apply to records required to be established or maintained by subpart R of part 1 of this chapter. Records that satisfy the requirements of subpart R of part 1 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 6. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C.141–149, 321–394, 467f, 679, 821, 1034, 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 7. In § 16.1, add the following entries in numerical order to paragraph (b)(2) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§ 1.1173, relating to the revocation of recognition of an accreditation body, and revocation of accreditation of a laboratory, with respect to food testing conducted under part 1, subpart R of this chapter.

§ 1.1174, relating to the issuance of a food testing order by FDA pursuant to § 1.1107(a)(2).

* * * * *

PART 129—PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER

■ 8. The authority citation for part 129 is revised to read as follows:

Authority: 21 U.S.C. 342, 348, 350k, 371, 374, 42 U.S.C. 264.

■ 9. Amend § 129.35 by revising paragraph (a)(3)(iii) to read as follows:

§ 129.35 Sanitary facilities.

* * * * *

(a) * * *

(3) * * *

(iii) Analysis of the sample may be performed for the plant by competent commercial laboratories (*e.g.,* Environmental Protection Agency (EPA) and State-certified laboratories), except that the analysis of the five samples from the same sampling site that originally tested positive for *E. coli,* as required by paragraph (a)(3) of this section, must be conducted under part 1, subpart R of this chapter.

* * * * *

Dated: September 30, 2019.

Norman E. Sharpless,

Acting Commissioner of Food and Drugs.

Dated: October 25, 2019.

Eric D. Hargan,

Deputy Secretary, Department of Health and Human Services.

[FR Doc. 2019–23870 Filed 11–1–19; 8:45 am]

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Part III

The President

Presidential Determination No. 2020–01 of October 18, 2019—Presidential Determination and Certification With Respect to the Child Soldiers Prevention Act of 2008
Presidential Determination No. 2020–02 of October 18, 2019—Presidential Determination With Respect to the Efforts of Foreign Governments Regarding Trafficking in Persons

Federal Register
Vol. 84, No. 213
Monday, November 4, 2019

Presidential Documents

Title 3—

The President

Presidential Determination No. 2020–01 of October 18, 2019

Presidential Determination and Certification With Respect to the Child Soldiers Prevention Act of 2008

Memorandum for the Secretary of State

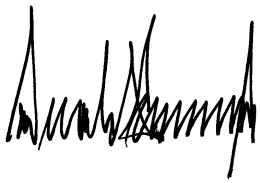
Pursuant to section 404 of the Child Soldiers Prevention Act of 2008 (22 U.S.C. 2370c–1) (CSPA), I hereby:

Determine that it is in the national interest of the United States to waive the application of the prohibition in section 404(a) of the CSPA with respect to Afghanistan and Iraq; to waive the application of the prohibition in section 404(a) of the CSPA with respect to the Democratic Republic of the Congo to allow for the provision of International Military Education and Training (IMET) and Peacekeeping Operations (PKO) assistance, to the extent the CSPA would restrict such assistance or support; to waive the application of the prohibition in section 404(a) of the CSPA with respect to Mali to allow for the provision of IMET and PKO assistance, the issuance of licenses for direct commercial sales of military equipment, and Department of Defense (DOD) support provided pursuant to 10 U.S.C. 333, to the extent the CSPA would restrict such assistance or support; to waive the application of the prohibition in section 404(a) of the CSPA with respect to Somalia to allow for the provision of IMET and PKO assistance and DOD support provided pursuant to 10 U.S.C. 333, to the extent the CSPA would restrict such assistance or support; to waive the application of the prohibition in section 404(a) of the CSPA with respect to South Sudan to allow for the provision of PKO assistance, to the extent the CSPA would restrict such assistance or support; and, to waive the application of the prohibition in section 404(a) of the CSPA with respect to Yemen to allow for the provision of PKO assistance and DOD support provided pursuant to 10 U.S.C. 333, to the extent the CSPA would restrict such assistance or support; and

Certify that the governments of the above countries are taking effective and continuing steps to address the problem of child soldiers.

Accordingly, I hereby waive such applications of section 404(a) of the CSPA.

You are authorized and directed to submit this determination to the Congress, along with the Memorandum of Justification, and to publish the determination in the *Federal Register*.



THE WHITE HOUSE,
Washington, October 18, 2019

[FR Doc. 2019–24195
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Presidential Documents

Presidential Determination No. 2020–02 of October 18, 2019

Presidential Determination With Respect to the Efforts of Foreign Governments Regarding Trafficking in Persons

Memorandum for the Secretary of State

Consistent with section 110 of the Trafficking Victims Protection Act of 2000 (22 U.S.C. 7107) (the ''Act''), as amended, I hereby determine as follows:

As provided for in section 110(d)(1)(A)(i) of the Act, and subject to the determinations below regarding assistance related to the Ebola virus disease and meeting minimum standards for the elimination of trafficking in persons, I determine that the United States will not provide nonhumanitarian, nontrade-related assistance to the Governments of Burundi, China, Equatorial Guinea, Eritrea, The Gambia, Iran, and Mauritania for Fiscal Year (FY) 2020 until such governments comply with the Act's minimum standards or make significant efforts to bring themselves into compliance with the minimum standards.

As provided for in section 110(d)(1)(A)(ii) of the Act, and subject to the determinations below regarding assistance related to the Ebola virus disease and meeting minimum standards for the elimination of trafficking in persons, I determine that the United States will not provide nonhumanitarian, nontrade-related assistance to, or allow funding for participation in educational and cultural exchange programs by officials or employees of, the Governments of Cuba, the Democratic People's Republic of Korea (DPRK), Russia, and Syria for FY 2020 until such governments comply with the Act's minimum standards for the elimination of trafficking or make significant efforts to bring themselves into compliance with the minimum standards.

As provided for in section 110(d)(1)(B) of the Act, and subject to the determinations below regarding assistance related to the Ebola virus disease and meeting minimum standards for the elimination of trafficking in persons, I hereby instruct the United States Executive Director of each multilateral development bank, as defined in the Act, and of the International Monetary Fund to vote against and use best efforts to deny any loan or other utilization of the funds of the respective institution (other than for humanitarian assistance; for trade-related assistance; or for development assistance that directly addresses basic human needs, is not administered by the government of such country, and confers no benefit to that government) for the Governments of Burundi, China, Cuba, the DPRK, Equatorial Guinea, Eritrea, The Gambia, Iran, Mauritania, Russia, Saudi Arabia, South Sudan, and Syria for FY 2020 until such governments comply with the Act's minimum standards or make significant efforts to bring themselves into compliance with the minimum standards.

Consistent with section 110(d)(4) of the Act, I determine that a partial waiver to allow assistance described in section 110(d)(1) of the Act for programs, projects, activities, and assistance to respond to the threat posed by the Ebola virus disease would promote the purposes of the Act or is otherwise in the national interest of the United States;

Consistent with section 110(d)(4) of the Act, I determine that a partial waiver to allow assistance described in section 110(d)(1) of the Act for programs, projects, activities, and assistance designed to meet the minimum standards for the elimination of trafficking in persons would promote the

purposes of the Act or is otherwise in the national interest of the United States;

Consistent with section 110(d)(4) of the Act, I determine that a partial waiver to allow Economic Support Fund (ESF) assistance, Democracy Fund (DF) assistance, and technical assistance under section 129 of the Foreign Assistance Act of 1961 with respect to Burma would promote the purposes of the Act or is otherwise in the national interest of the United States;

Consistent with section 110(d)(4) of the Act, I determine that a partial waiver to allow assistance described in section 110(d)(1)(A)(i) of the Act with respect to the Democratic Republic of the Congo (DRC)—with the exception of Foreign Military Financing, Foreign Military Sales (FMS), and excess defense articles—would promote the purposes of the Act or is otherwise in the national interest of the United States;

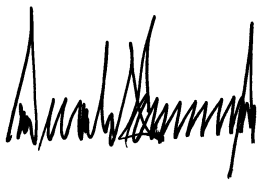
Consistent with section 110(d)(4) of the Act, I determine that a partial waiver to allow FMS with respect to Saudi Arabia would promote the purposes of the Act or is otherwise in the national interest of the United States;

Consistent with section 110(d)(4) of the Act, I determine that a partial waiver to allow Peacekeeping Operations (PKO) assistance with respect to South Sudan would promote the purposes of the Act or is otherwise in the national interest of the United States;

Consistent with section 110(d)(4) of the Act, I determine that the provision of all programs, projects, and activities described in section 110(d)(1)(A)(i) of the Act with respect to the Governments of Belarus, Bhutan, Comoros, Papua New Guinea (PNG), Turkmenistan, and Venezuela would promote the purposes of the Act or is otherwise in the national interest of the United States; and

Consistent with section 110(d)(4) of the Act, I determine that providing the assistance described in section 110(d)(1)(B) of the Act to Belarus, Bhutan, Burma, Comoros, the DRC, PNG, Turkmenistan, and Venezuela would promote the purposes of the Act or is otherwise in the national interest of the United States.

You are authorized and directed to submit this determination, the certification required by section 110(e) of the Act, and the Memorandum of Justification, on which I have relied, to the Congress, and to publish the determination in the *Federal Register*.



THE WHITE HOUSE,
Washington, October 18, 2019

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S. 1196/P.L. 116–66
To designate the facility of the United States Postal Service located at 1715 Linnerud Drive in Sun Prairie, Wisconsin, as the ''Fire Captain Cory Barr Post Office Building''. (Oct. 31, 2019; 133 Stat. 1127)
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