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The President

Patriot Day, 2019

By the President of the United States of America

A Proclamation

On Patriot Day, we solemnly remember the nearly 3,000 people who perished on September 11, 2001. With gratitude, we honor the brave first responders, resolute members of our military, and ordinary Americans who showed extraordinary courage to save others on that fateful day. We will always be grateful for the heroic men and women of our Armed Forces who fought in defense of our country in the aftermath of the largest terrorist attack on American soil, and we will never forget those who made the ultimate sacrifice to defend our liberty and freedom.

Many Americans vividly recall the precise moment when terrorists killed our fellow Americans at the World Trade Center in New York City; at the Pentagon in Arlington, Virginia; and on a quiet field in Shanksville, Pennsylvania. A beautiful September morning was marred by stark disbelief, agonizing sorrow, and profound suffering. America's strength, courage, and compassion, however, never wavered. First responders instantly rushed into harm's way to save their fellow Americans from the wreckage of the attacks, the passengers and crew of United Flight 93 decisively fought back and saved countless lives at the cost of their own, and Americans from across the country provided aid, assistance, and comfort to those in need. Against the backdrop of cowardly acts of terror, America once again demonstrated to the world the unmatched strength of our resolve and the indomitable power of our character.

This year, I was proud to sign into law the Permanent Authorization of the September 11th Victim Compensation Fund Act. This bipartisan legislation, named in honor of New York first responders Officer James Zadroga, Firefighter Ray Pfeifer, and Detective Luis Alvarez, permanently reauthorizes compensation for victims and their families, first responders, and those on the front lines of rescue and recovery operations at Ground Zero. Through this legislation, our Nation is fulfilling our sacred duty to those who risked their lives for their fellow Americans on that infamous September day 18 years ago.

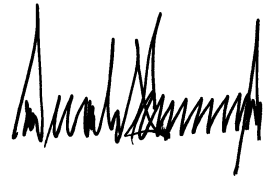
Our prayers will continue for the survivors who still bear physical and emotional wounds and for the families who lost loved ones. We also pray for the members of our Armed Forces who risk their lives in service to our country and for the first responders who work tirelessly to ensure the safety of others. Today, let us remember that our Union—forged and strengthened through adversity—will never be broken and that the immeasurable sacrifices of our patriots will never be forgotten.

By a joint resolution approved December 18, 2001 (Public Law 107–89), the Congress has designated September 11 of each year as “Patriot Day.”

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, do hereby proclaim September 11, 2019, as Patriot Day. I call upon all departments, agencies, and instrumentalities of the United States to display the flag of the United States at half-staff on Patriot Day in honor of the individuals who lost their lives on September 11, 2001. I invite the Governors of the United States and its Territories and interested organizations and individuals to join in this observance. I call upon the

people of the United States to participate in community service in honor of those our Nation lost, to observe this day with appropriate ceremonies and activities, including remembrance services, and to observe a moment of silence beginning at 8:46 a.m. Eastern Daylight Time to honor the innocent victims who perished as a result of the terrorist attacks of September 11, 2001.

IN WITNESS WHEREOF, I have hereunto set my hand this tenth day of September, in the year of our Lord two thousand nineteen, and of the Independence of the United States of America the two hundred and forty-fourth.



Presidential Documents

Memorandum of September 6, 2019—Providing an Order of Succession Within the Council on Environmental Quality

Correction

In Presidential document 2019–19930 beginning on page 48227 in the issue of Thursday, September 12, 2019, make the following correction:

On page 48227, in the document heading, the word “Secession” should read “Succession”.

[FR Doc. C1–2019–19930
Filed 9–13–19; 8:45 a.m.]
Billing Code 1301–00–D

Rules and Regulations

Federal Register

Vol. 84, No. 179

Monday, September 16, 2019

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

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 54

[No. AMS-LP-16-0080]

Amendments to the Regulations Governing Meats, Prepared Meats, and Meat Products (Grading, Certification, and Standards)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule informs the public that the U.S. Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) is amending its regulations to update a number of outdated administrative and organizational references, clarify agency action as it relates to the withdrawal or denial of service, update the official shields and grademarks associated with the grading service, and make reference to the use of instrument grading equipment as a means of determining official grades on beef and lamb carcasses.

DATES: This final rule is effective September 16, 2019.

FOR FURTHER INFORMATION CONTACT: Dana K. Stahl, Chief, Grading Services Branch, QAD, Livestock and Poultry Program, AMS, USDA; 1400 Independence Avenue SW; Room 3932-S, Stop 0258, Washington, DC 20250-0258; (202) 690-3169; or email to dana.stahl@usda.gov.

SUPPLEMENTARY INFORMATION:

Executive Orders 12866 and 13771, and Regulatory Flexibility Act

This rulemaking does not meet the definition of a significant regulatory action contained in section 3(f) of Executive Order 12866 and is not subject to review by the Office of Management and Budget (OMB). Additionally, because this 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).

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) [5 U.S.C. 601 *et seq.*], the Administrator of AMS considered the economic effect of this action on small entities and determined that this final rule does not have a significant economic impact on a substantial number of small business entities, because the user-fee services that are subject to the requirements of this regulation are not subject to scalability based on the business size. 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 burdened.

Currently, approximately 235 applicants subscribe to AMS's voluntary, user fee services. The U.S. Small Business Administration's Table of Small Business Size Standards matched to the North American Industry Classification System (NAICS) Codes identifies small business size by average annual receipts or by the average number of employees at a firm. This information can be found at 13 CFR parts 121.104, 121.106, and 121.201.

AMS requires that all applicants for service provide information about their company for the purpose of processing bills. Information collected from an applicant includes company name, address, billing address, and similar information. AMS does not collect information about the size of the business. However, based on working knowledge of these operations, AMS estimates that roughly 72 percent of current applicants may be classified as small entities. It is not anticipated that this action will impose additional costs to applicants, regardless of size. Current applicants will not be required to provide any additional information to receive service. The effects of this final rule are not expected to be disproportionately greater or lesser for small applicants than for large applicants.

AMS is committed to complying with the E-Government Act of 2002 [44 U.S.C. 101] 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. Accordingly, AMS developed options for companies requesting service to do so electronically.

The USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this final rule.

Congressional Review Act

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

Executive Order 13175

This action has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

Executive Order 12988

This final rule has been reviewed under Executive Order (E.O.) 12988, Civil Justice Reform. This final rule is not intended to have retroactive effect. The E.O. prohibits states or political subdivisions of a state to impose any requirement that is in addition to, or inconsistent with, any requirement of the E.O. There are no civil justice implications associated with this final rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 [44 U.S.C. Chapter 35], this final rule will not change the information collection and recordkeeping requirements previously approved and would not impose additional reporting or recordkeeping burden on users of these voluntary services.

The information collection and recordkeeping requirements of this part have been approved by OMB under 44 U.S.C. Chapter 35 and have been assigned OMB Control Number 0581-0128.

In September 2014, three separate OMB collections—OMB 0581–0127, OMB 0581–0124, and OMB 0581–0128—were merged, such that the current OMB 0581–0128 pertains to Regulations for Voluntary Grading, Certification, and Standards and includes 7 CFR parts 54, 56, 62, and 70.

Background and Revisions

The Agricultural Marketing Act of 1946 (7 U.S.C. 1621 *et seq.*), herein after referred to as the “Act,” directs and authorizes the Secretary of Agriculture to facilitate the competitive and efficient marketing of agricultural products. AMS programs support a strategic marketing perspective that adapts product and marketing decisions to consumer demands and changes in domestic and international marketing practices and incorporates emerging technology. AMS provides impartial grading and certification services that ensure agricultural products meet specified requirements. These services are voluntary, with users paying for the cost of the requested service. AMS grading services verify that product meets USDA grade standards (*e.g.*, USDA Choice) and certify that products meet requirements defined by the company or another third-party. Product characteristics such as manner of cut, color, and other quality attributes can be directly examined by an AMS employee or an authorized agent to determine if product requirements have been met. The product can be identified as “USDA Prime,” “USDA Choice,” “USDA Select,” “USDA Certified,” “USDA Accepted as Specified,” or “USDA Further Processing Certification Program.”

Administrative and Organizational Revisions

In 2012, an organizational merger within AMS combined the Livestock and Seed Program and Poultry Programs into the Livestock, Poultry, and Seed (LPS) Program. Subsequently, the LPS Program created the Quality Assessment Division (QAD) to oversee services carried out by the Audit Services Branch, Grading Services Branch, Standardization Branch, and the Business Operations Branch. The Grading Services Branch administers grading and certification services that were performed by the former Meat Grading and Certification Branch of the former Livestock and Seed Program and the former Grading Branch of Poultry Programs. In 2018, another organizational change caused the LPS Program to be renamed the Livestock and Poultry Program.

Meat grading and certification activities are carried out under 7 CFR 54, while poultry and shell egg grading and certification activities are carried out under 7 CFR 70 and 7 CFR 56, respectively.

Through this rulemaking, AMS will update a number of administrative and organizational references to reflect the current terminology and structure of AMS. These amendments include amending § 54.1 to change the LPS Program to the Livestock and Poultry Program. Certain terms and definitions will be added to, updated in, or deleted from § 54.1 to reflect the current organizational structure within the Agency. The term and definition for *Livestock* will be removed from the regulation because the use of this definition was fundamentally the same as the definition of *Animals*. The term and definitions for *Contract verification service* will be removed from § 54.1 because this service is no longer provided, and a conforming change will be made to § 54.4 *Kind of service*. The definition for *Animals* will be revised to add “bison,” as the Agency certifies bison; *Chief* will be revised to identify the Grading Services Branch Chief; *Division* will be revised to identify QAD and appropriately reflect its level within the organization; *Meat by-products* will be revised to exclude brain derived from ruminant animals, which is no longer allowed per food safety regulations; and the term *Standards* will be replaced with *Official standards*, and its definition will be revised for consistency within the regulation. The terms *Yield grade* and *Appeal service* and their respective definitions will be added to identify the different types of grading service offered under the regulations. The terms *Program* and *Deputy Administrator* and their respective definitions will be added to appropriately recognize the office and leadership within the current organizational structure of the Agency.

Since this regulation has not received significant revisions for some time, AMS is revising it to make it consistent with The Plain Writing Act of 2010 [Pub. L. 111–274]. To accomplish this, AMS is focusing on appropriate pronoun use, omitting unnecessary words, and writing short sentences.

To reflect organizational changes and for consistency with other changes to this regulation, AMS will amend § 54.4 *Kind of service*, § 54.6 *How to obtain service*, § 54.7 *Order of furnishing service*, § 54.8 *When request for service deemed made*, § 54.9 *Withdrawal of application or request for service*, and § 54.10 *Authority of agent*.

AMS will also amend § 54.5 *Availability of service* by removing language that states service will be provided without discrimination, as this is a duplicative statement of a requirement that is mandated through Departmental regulations, not by AMS.

AMS will amend § 54.6 *How to obtain service* by increasing the length of time between cancellation of commitment service and reapplication for commitment service from 1 to 2 years and clarifying that the applicant is responsible for reimbursing relocation costs incurred by the Agency to transfer the grader.

AMS will remove the reference to the Medium grade for lamb, yearling lamb, mutton, and pork carcasses in § 54.11(a)(1)(vii). The official standards for grades of lamb and mutton carcasses were amended in October 1940 (Amendment No. 1 to S.R.A. 123) to change the grade designations Medium and Common to Commercial and Utility, respectively. In April 1968, the official standards for pork carcasses were revised and the former Medium and Cull grades were combined and renamed U.S. Utility. Removing the reference to Medium in § 54.11(a)(1)(vii) aligns the regulatory language with the language contained within the official standards.

Clarify Agency Action on Denial or Withdrawal of Service

AMS will create a stair-stepped approach regarding denial or withdrawal of Grading Services Branch services. As written, § 54.11 requires AMS to go before an administrative law judge to hear a case for an applicant accused of misconduct before any action can be taken; the process and actions currently identified in this part limit AMS’s ability to effectively manage its services, including denying, withdrawing, or suspending services in a timely manner when warranted for reasons of misconduct. Therefore, AMS is clarifying that it shall rely first on the Supplemental Rules of Practice in 7 CFR 50 and then, if necessary, use the Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes set forth in 7 CFR 1.130 through 1.151 when denying, withdrawing, or suspending services to applicants. An applicant will still have an opportunity for a hearing before an administrative law judge before any permanent action occurs.

Other Amendments to the Regulation

The regulations outlined in this part are intended to describe to the public how AMS provides grading and

certification services and the related processes, not provide instruction to employees or repeat requirements covered by another Federal regulation. Accordingly, AMS will remove and reserve for future use § 54.12 *Financial interest of official grader*. USDA graders and other employees are required to meet and maintain Departmental ethics requirements; therefore, AMS has determined that it is unnecessary to maintain this administrative item in this regulation. AMS will remove and reserve § 54.14 *Official certificates*, which removes the Agricultural Products Certificate Form LS-5-3 and the Applicant Charges Certificate Form LS-5-5. These forms were discontinued in 2009, and the information they contained is now entered into a database. If an applicant requires an official certificate from USDA, an official memorandum is issued containing the pertinent information.

In 2001, vision-based instrument technology was approved for use in the official determination of the size of the ribeye area. In 2007, it was approved for yield grade determination, and in 2009, it was approved for marbling assessment. Although this technology has been used as an aid in the application of official USDA beef grades since 2001, the current regulations make no mention of it. AMS considers the use of instrument technology to be an important option for determining degrees of marbling in meat carcasses and yield and, therefore, is adding a reference to it in § 54.15.

AMS will appropriately identify and reference figures within § 54.17. Currently, multiple figures in that section contain the same label, Figure 1, which makes it difficult to accurately reference any one particular figure. AMS will remove the Carcass Data Service orange ear tag from § 54.17, because the Agency no longer prints or maintains them and instead allows cattle enrolled in the Carcass Data Service to be identified through other approved methods. AMS will appropriately identify and reference in § 54.17 the USDA Further Processing Certification Program shield used to identify product produced under the USDA Further Processing Certification Program. Additionally, AMS will amend language within this section to accurately identify the USDA Hold tag that is now used in place of the USDA Product Control tag. The tag is now red in color as opposed to orange.

Within § 54.19, AMS will remove the heading *APPEAL SERVICE*, rename § 54.19 as *Appeal of a grading service decision*, reassign amended language from §§ 54.20 through 54.26 under

§ 54.19 (a) through (h), and subsequently reserve §§ 54.21 through 54.26.

AMS will rename § 54.20 *Exemptions*. The amendments will identify the requirements within the regulation where exemptions are most commonly provided and identify an option for exemptions as seen fit by the Director. It also will require the Director to approve all exemptions to this regulation. AMS will make conforming changes to §§ 54.4 *Kind of service*, 54.5 *Availability of service*, and 54.13 *Accessibility and refrigeration of products; access to establishments*.

Together, amendments to §§ 54.5 *Availability of service*, 54.13 *Accessibility and refrigeration of products; access to establishments*, and § 54.20 *Exemptions* clarify the grading of meat in less-than-carcass form, and further, that the grading of imported carcasses is allowable only under an exemption approved by the Director. For clarity, the requirements for grading of imported carcasses are addressed within §§ 54.20.

AMS will remove and reserve § 54.30 *Errors in service*. AMS proposed that the subject covered in this § 54.30 is most appropriately covered under a policy or procedure rather than a regulation.

Lastly, AMS will replace the title and language of § 54.31 *Uniforms* with the title *OMB Control Number*. AMS believes the subject of uniforms is more appropriate under a policy rather than a regulation. AMS will add language under this section that clearly identifies the OMB control number, OMB 0581-0128, assigned to this regulation in accordance with the Paperwork Reduction Act.

Summary of Comments

A proposed rule to amend the Regulations Governing Meats, Prepared Meats, and Meat Products (Grading, Certification, and Standards) was published in the **Federal Register** (84 FR 1641) on February 5, 2019. Comments on the proposed rule were solicited from interested parties until April 8, 2019. AMS received 12 comments: 8 from consumers, 1 from an industry company, and 3 from industry trade organizations. One of the 12 comments was outside the scope of the regulations.

Three consumer commenters supported all the amendments as beneficial for consumers and producers of meat products, while two consumer commenters were supportive of the amendments with the exception of 54.13(d), which requires that applicants for grading service make products, records, and equipment accessible so

that graders may perform their duties effectively. This includes offering product for grading or certification that is, at a minimum, 90 percent acceptable. The two commenters suggested that this number should be increased to 100 percent. In response, AMS will maintain the requirement as written in the proposed rule, as 90 percent reflects a practical and achievable goal that effectively limits ineligible product from being offered for grading and certification.

The 3 industry commenters and 1 company commenter generally supported the changes in the proposed rule, with a few exceptions.

One commenter pointed out that the definition in § 54.1 for “Institutional Meat Purchase Specifications” should be amended to include quotation marks to designate “IMPS” as an acronym and the definition of “meat by-products” should be consistent with that used by the Food Safety and Inspection Service. In response to these suggestions, the Agency is revising the proposed language for the definitions of “Institutional Meat Purchase Specifications” and “meat by-products.”

One commenter suggested that AMS provide background on the change to the reimbursement requirements in § 54.6 from 1 year to 2 years, stating that AMS did not provide justification or an impact analysis for this change. AMS proposed this change, requiring that the applicant be responsible for the cost of relocating a grader should it cancel its commitment service and then reinstate it within 2 years, in light of the significant expense and disruption to the Agency of relocating a grader multiple times within a short period of time, based on previous experience. Expanding this requirement to a 2-year timeframe will help AMS continue to provide consistent service and a stable work environment for AMS employees. Therefore, AMS will maintain the requirement as amended in the proposed rule.

Regarding § 54.11, one commenter recommended revising language in the preamble of the final rule to show the distinct order of AMS procedures when denying, withdrawing, or suspending service that “reflects agency practice and does not represent a tangible change.” AMS agrees and has added clarifying language to the preamble.

One commenter suggested a revision in 54.13(a) that would replace the word “any” with “covered” or a similar phrase to clarify the regulatory intent when talking about marks of grade or compliance. AMS has determined not to make this change. By referencing “any

marks” the Agency continues to accept defined marks that are recognized within the industry and have replaced official stamps for some methods of identification. One example is an ink brush stroke on the hock to identify a carcass meeting the Angus breed phenotypic specification; this practice reduces the amount of ink on the carcass round and therefore reduces trim and waste within the packing sector.

One industry commenter supported the reference to instrument grading in section in § 54.15 and urged USDA to ensure consistency of instrument grading calibration.

One industry commenter supported the proposed changes to the marketing grade terms (e.g., Prime, Choice, Select) to indicate the level of quality, while two consumer commenters opposed the changes, suggesting “terms such as level 1, level 2, and level 3 may make the quality grade meanings clearer to consumers.” In response to these comments, AMS will keep the proposed changes so that marketing grade terms remain consistent with the past as the terms are widely known and recognized by the industry, consumers, and foreign trading partners.

Several comments were received regarding the proposed changes to § 54.5 and § 54.20 with respect to grading of imported carcasses. One commenter asked for clarification on whether, as a result of the proposed changes, the eligibility of imported product would change significantly. The answer is no. The regulations and AMS procedures allow the Agency to grant exemptions to grade imported product in carcass form, enabling AMS to use all parts of the official standards to determine the appropriate grade. AMS is clarifying that exemptions have always been required for the official grading of imported carcasses since § 54.5 requires that carcasses come from animals slaughtered in establishments that are federally inspected or operated under state meat inspection. In the final rule, this requirement is maintained under § 54.5 and language is added to clarify that the grading of imported carcasses is allowed only under an exemption approved by the Director.

Two commenters supported the general guidance in § 54.20 allowing additional flexibility under exemptions granted by the Agency. One commenter opposed the proposed amendment to § 54.5 that service “may be furnished” instead of “will be furnished” for imported meat, suggesting instead that the phrase be changed to “shall be provided.” Another commenter recommended a change to the proposed

language in § 54.20 authorizing the Director to issue exemptions, requesting that “shall issue” be added. After consideration, AMS will proceed with language of the proposed rule in § 54.5 and § 54.20 with minor changes. The Agency believes that maintaining flexibility in the process by which the Director may approve or deny exemptions is necessary to enhance commerce while ensuring decisions are for good cause and based upon the supporting documentation provided by the applicant. Changing the word “will” to “may” supports the Agency’s due diligence to ensure minimal impact upon the industry should an exemption be granted and to deny requests if determined otherwise.

One commenter supported the language in § 54.20 that provides an exemption allowing for the grading of meat in other-than-carcass form “if the class, grade, and other quality attributes may be determined under the applicable standards.” This commenter suggested that as long as an establishment can demonstrate that products presented for grading are of the proper class and maturity, and the grade can be determined based on the quality attributes of the meat, there is no need to limit grading services to whole carcasses. The commenter referenced an exemption that AMS granted in 2017 for the grading of ribs and loins imported from Mexico. The commenter also asked AMS to clarify, in the final rule or in guidance, what criteria must be satisfied to demonstrate an animal’s class when meat is presented for grading in other-than-carcass form.

In response, AMS maintains that the official standards are written in terms of carcasses and sides, and thus the grading of product in less-than-carcass form is generally contrary to the standards. AMS maintains the flexibility to grant exemptions for product presented in other-than-carcass form, but these exemptions are typically for religious reasons where a whole carcass has been presented for grading as quarters instead of sides. In contrast, AMS maintains that subprimal parts, such as ribs and loins, present insufficient criteria by which a grader may make an adequate class or quality determination. Therefore, AMS will maintain the proposed language in § 54.20 with one clarifying change: references to “meat from imported animals” and “imported meat” are changed to “imported carcasses” for clarity and accuracy.

Coinciding with the publication of this final rule, AMS will be amending its procedures (QAD Procedure 504 Import Grading) accordingly.

One industry commenter opposed any reciprocity of official standards and services of USDA beef grades outside the U.S. and also opposed other countries utilizing USDA’s system and associated terms. While AMS considers this comment to be outside the scope of this rulemaking, we recognize the industry’s concerns.

List of Subjects in 7 CFR 54

Food grades and standards, Food labeling, Meat and meat products, Poultry and poultry products.

For the reasons set forth in the preamble, AMS amends 7 CFR part 54 as follows:

PART 54—MEATS, PREPARED MEATS, AND MEAT PRODUCTS (GRADING, CERTIFICATION, AND STANDARDS)

- 1. The authority citation for 7 CFR 54 continues to read as follows:

Authority: 7 U.S.C. 1621–1627.

- 2. Amend § 54.1 by:
 - A. Revising the section heading.
 - B. Revising the definitions of “Administrator,” “Animals,” “Branch,” “Chief,” “Director,” “Division,” “Institutional Meat Purchase Specifications,” “Meat by-products”, and “Service”.
 - C. Adding in alphabetical order the definitions “Appeal service,” “Deputy Administrator,” “Official standards,” and “Program”.
 - D. Removing the definitions for “Contract verification service,” “Livestock,” “Standards”.

The revisions and additions read as follows:

§ 54.1 Meaning of words and terms defined.

* * * * *

Administrator. The Administrator of the Agricultural Marketing Service (AMS), or any officer or employee of the AMS to whom authority has been or may be delegated to act in the Administrator’s stead.

* * * * *

Animals. Bison, cattle, goats, sheep, swine, or other species identified by the Administrator.

* * * * *

Appeal service. Appeal service is a redetermination of the class, grade, other quality, or compliance of product when the applicant for the appeal service formally challenges the correctness of the original determination.

* * * * *

Branch. The Grading Services Branch of the Division.

* * * * *

Chief. The Chief of the Grading Services Branch, or any officer or employee of the Branch to whom authority has been or may be delegated to act in the Chief's stead.

* * * * *

Deputy Administrator. The Deputy Administrator of the Program, or any other officer or employee of the Program to whom authority has been or may be delegated to act in the Deputy Administrator's stead.

Director. The Director of the Division, or any officer or employee of the Division to whom authority has been or may be delegated to act in the Director's stead.

* * * * *

Division. The Quality Assessment Division of the Livestock and Poultry Program.

* * * * *

Institutional Meat Purchase Specifications. Specifications describing various meat cuts, meat products, and meat food products derived from species covered in the definition of *Animals* above, commonly abbreviated "IMPS," and intended for use by any meat procuring activity. For labeling purposes, only product certified by the Grading Services Branch may contain the letters "IMPS" on the product label.

* * * * *

Meat by-products. Any part capable of use as human food, other than meat, which has been derived from one or more cattle, sheep, swine, or goats.

* * * * *

Official standards. Official standards refer to the United States Standards for Grades of Carcass Beef; the United States Standards for Grades of Veal and Calf Carcasses; the United States Standards for Grades of Lamb, Yearling Mutton, and Mutton Carcasses; and/or the United States Standards for Grades of Pork Carcasses.

* * * * *

Program. The Livestock and Poultry Program of the Agricultural Marketing Service.

Service. Services offered by the Grading Services Branch such as Grading Service, Certification Service, and Carcass Data Service.

* * * * *

Yield grade. The indicated yield of closely trimmed (½ inch fat or less), boneless retail cuts expected to be derived from the major wholesale cuts (round, sirloin, short loin, rib, and square-cut chuck) of a carcass.

■ 3. Revise § 54.4 to read as follows:

§ 54.4 Kind of service.

(a) Grading Service consists of the determination, certification, and identification of the class, grade, or other quality attributes of products under applicable official standards.

(b) Certification Service consists of the determination, certification, and identification of products to an approved specification. Determination of product compliance with specifications for ingredient content or method of preparation may be based upon information received from the inspection system having jurisdiction over the products involved.

(c) Carcass Data Service consists of the evaluation of carcass characteristics of animals identified with an approved ear tag to applicable official standards or specifications, and the recording and transmitting of the associated data to the applicant or a party designated by the applicant.

■ 4. Revise § 54.5 to read as follows:

§ 54.5 Availability of service.

Service under these regulations may be made available to products shipped or received in interstate commerce. It also may be made available to the products not shipped or received if the Director or Chief determines that the furnishing of service for such products will facilitate the marketing, distribution, processing, or utilization of agricultural products through commercial channels. Service will be furnished for products only if they were derived from animals slaughtered in federally inspected establishments or establishments operated under state meat inspection in a state other than one designated in 9 CFR 331.2. Service may be furnished for imported carcasses only if an exemption to do so is granted by the Director as described in § 54.20.

■ 5. Revise § 54.6 to read as follows:

§ 54.6 How to obtain service.

(a) *Application.* Any person may apply for service with respect to products in which he or she has a financial interest by completing the required application for service. In any case in which the service is intended to be furnished at an establishment not operated by the applicant, the application shall be approved by the operator of such establishment and such approval shall constitute an authorization for any employee of the Department to enter the establishment for the purpose of performing his or her functions under the regulations. The application shall include:

(1) Name and address of the establishment at which service is desired;

(2) Name and mailing address of the applicant;

(3) Financial interest of the applicant in the products, except where application is made by a representative of a Government agency in the representative's official capacity;

(4) Signature of the applicant (or the signature and title of the applicant's representative);

(5) Indication of the legal status of the applicant as an individual, partnership, corporation, or other form of legal entity; and

(6) The legal designation of the applicant's business as a small or large business, as defined by the U.S. Small Business Administration's North American Industry Classification System (NAICS) Codes.

(b) *Notice of eligibility for service.* The applicant will be notified whether the application is approved or denied.

(c) *Request by applicant for service:*

(1) *Noncommitment.* Upon notification of the approval of an application for service, the applicant may, from time-to-time as desired, make oral or written requests for service to be furnished with respect to specific products. Such requests shall be made at an office for grading, either directly or through an AMS employee.

(2) *Commitment.* If desired, the applicant may request to enter into an agreement with AMS to furnish service on a weekly commitment basis, where the applicant agrees to pay for 8 hours of service per day, 5 days per week, Monday through Friday, excluding Federal legal holidays occurring Monday through Friday on which no grading and certification services are performed, and AMS agrees to make an official grader available to provide service for the applicant. However, AMS reserves the right to use any official grader assigned to a commitment applicant to perform service for other applicants when, in the opinion of the Chief, the official grader is not needed to perform service for the commitment applicant. In those instances, the applicant will not be charged for the work of the grader assigned to his or her facility.

(3) If an applicant who terminates commitment grading service requests service again within a 2-year period from the date of the initial termination, the applicant will be responsible for all relocation costs associated with the grader assigned to fulfill the new service agreement. If more than one applicant is involved, expenses will be prorated according to each applicant's committed portion of the official grader's services.

■ 6. Revise § 54.7 to read as follows:

§ 54.7 Order of furnishing service.

Service shall be furnished to applicants in the order in which requests are received. Preference will be given, when necessary, to requests made by any government agency or any regular user of the service, and to requests for appeal service under § 54.19.

■ 7. Revise § 54.8 to read as follows:

§ 54.8 When request for service deemed made.

A request for service is considered made when received by the designated office as identified on the Application for Service form. Records showing the date and time of the request shall be made and maintained in the designated office.

■ 8. Revise § 54.9 to read as follows:

§ 54.9 Withdrawal of application or request for service.

An application or a request for service may be withdrawn by the applicant at any time before the application is approved or prior to performance of service. In accordance with §§ 54.27 and 54.28, any expenses already incurred by AMS in connection with the review of an application or fulfilling a request for service are the responsibility of the applicant.

■ 9. Revise § 54.10 to read as follows:

§ 54.10 Authority of agent.

Proof that any person making an application or a request for service on behalf of any other person has the authority to do so may be required at the discretion of the Director or Chief.

■ 10. Amend § 54.11 by revising the section heading, paragraph (a)(1) introductory text, and paragraphs (a)(1)(i) through (iii), (vii), (x), and (a)(2) to read as follows:

§ 54.11 Denial, conditional withdrawal, or suspension of service.

(a) * * *

(1) *Basis for denial or withdrawal.* An application or a request for service may be rejected, or the benefits of the service may be otherwise denied to, or withdrawn from, any person who, or whose employee or agent in the scope of the individual's employment or agency:

(i) Has willfully made any misrepresentation or has committed any other fraudulent or deceptive practice in connection with any application or request for service;

(ii) Has given or attempted to give, as a loan or for any other purpose, any money, favor, or other thing of value, to any employee of the Department authorized to perform any function;

(iii) Has interfered with or obstructed, or attempted to interfere with or to obstruct, any employee of the Department in the performance of his or her duties under the regulations by intimidation, threats, assaults, abuse, or any other improper means;

* * * * *

(vii) Has applied the designation "US" or "USDA" and "Prime," "Choice," "Select," "Good," "Standard," "Commercial," "Utility," "Cutter," "Canner," "Cull," "No. 1," "No. 2," "No. 3," "No. 4," "Yield Grade 1," "Yield Grade 2," "Yield Grade 3," "Yield Grade 4," "Yield Grade 5," and "USDA Accepted as Specified," by stamp or text enclosed within a shield, or brand directly on any carcass, wholesale cut, or retail cut of any carcass, or has applied the aforementioned designations including "USDA Certified," and "USDA Further Processing Certification Program" on the marketing material associated with any such product as part of a grade designation or product specification;

* * * * *

(x) Has in any manner not specified in this paragraph violated subsection 203(h) of the Act: *Provided*, that paragraph (a)(1)(vi) of this section shall not be deemed to be violated if the person in possession of any item mentioned therein notifies the Director or Chief without delay that the person has possession of such item and, in the case of an official device, surrenders it to the Chief, and, in the case of any other item, surrenders it to the Director or Chief or destroys it or brings it into compliance with the regulations by obliterating or removing the violative features under supervision of the Director or Chief: *And provided further*, that paragraphs (a)(1) (ii) through (ix) of this section shall not be deemed to be violated by any act committed by any person prior to the making of an application of service under the regulations by the principal person. An application or a request for service may be rejected or the benefits of the service may be otherwise denied to, or withdrawn from, any person who operates an establishment for which that person has made application for service if, with the knowledge of such operator, any other person conducting any operations in such establishment has committed any of the offenses specified in paragraphs (a)(1)(i) through (x) of this section after such application was made. Moreover, an application or a request for service made in the name of a person otherwise eligible for service under the regulations may be rejected, or the benefits of the service may be otherwise

denied to, or withdrawn from, such a person: (A) In case the service is or would be performed at an establishment operated:

(1) By a corporation, partnership, or other person from whom the benefits of the service are currently being withheld under this paragraph; or

(2) By a corporation, partnership, or other person having an officer, director, partner, or substantial investor from whom the benefits of the service are currently being withheld and who has any authority with respect to the establishment where service is or would be performed; or

(B) In case the service is or would be performed with respect to any product with which any corporation, partnership, or other person within paragraph (a)(1)(x)(A)(1) of this section has a contract or other financial interest.

(2) *Procedure.* All cases arising under this paragraph shall be initially conducted in accordance with the Supplemental Rules of Practice in part 50 of this chapter. Any issue unable to be resolved under part 50 of this chapter shall be resolved or handled in accordance with the Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes set forth in §§ 1.130 through 1.151 of this title.

* * * * *

§ 54.12 [Removed and Reserved]

■ 11. Remove and reserve § 54.12.

■ 12. Revise § 54.13 to read as follows:

§ 54.13 Accessibility and refrigeration of products; access to establishments; suitable work environment; and access to records.

(a) The applicant shall make products easily accessible for examination, with appropriate and adequate illuminating facilities, in order to disclose their class, grade, other quality characteristics, and compliance with official standards or other contractual requirements for which service is being provided. Supervisors of grading and other employees of the Department responsible for maintaining uniformity and accuracy of service shall have access to all parts of establishments covered by approved applications for service under the regulations, for the purpose of examining all products in the establishments that have been or are to be graded or examined for compliance with specifications or which bear any marks of grade or compliance.

(b) Grading service will be furnished only for meat that an official grader determines is chilled so that grade factors are developed to the extent that

a proper grade determination can be made in accordance with the official standards. Meat that is presented in a frozen condition is not eligible for a grade determination. Meat of all eligible species shall be graded only in the establishment where the animal was slaughtered or initially chilled (except for veal and calf carcasses, which will be graded only after the hide is removed and only in the establishment where such removal occurs).

(c) Applicants are responsible for providing a work environment where official graders are not subjected to physical and/or verbal abuse, or other elements that could have a negative effect on providing an unbiased, third-party evaluation. Applicants shall designate primary company representatives to discuss grade placements and certification determinations with official graders.

(d) Applicants will make products and related records (approved labeling, technical proposals, quality plans, specifications, end product data schedules, grade volume information, etc.) easily accessible and provide assistance and any equipment necessary to accomplish the requested services. Equipment may include storage lockers/cabinets, branding ink, certified scales, food blenders, processors, grinders, sampling containers, sanitation equipment, thermometers, adequate lighting, weight tags, display monitors, video equipment for monitoring live animal schedules, etc. When offering product for grading or certification, applicants must ensure a minimum of 90 percent acceptable product.

(e) Applicants will provide a metal cabinet(s) or locker(s) for the secure storage of official meat grading equipment and identification devices for each official meat grader assigned to their establishment. Such cabinet(s) or locker(s) must be capable of being locked with a Government-owned lock and be located in an easily accessible and secure location within the applicant's establishment.

§ 54.14 [Removed and Reserved]

■ 13. Remove and reserve § 54.14.

§ 54.15 Instrument grading.

■ 14. Revise § 54.15 to read as follows:

§ 54.15 Instrument grading.

(a) Applicants may use USDA-approved technologies to augment the official USDA grading process for approved species presented for official grading. This voluntary program may be utilized by a plant at its discretion but must comply with QAD procedures to be recognized and relied upon by the official grader in conducting official duties.

(b) Applicants have the option to augment quality and yield grading services through the use of vision-based instrument technology. Instrument grading may be used as an option for determining degrees of marbling and yield factors for meat carcasses. AMS approves the grading instrument itself and its use within individual applicant facilities. Applicants may contact grading supervision to initiate the process for in-plant approval. The process for instrument grading approval at an applicant's facility is dictated through internal procedures. Final

determination of quality and yield grades is made by the official grader.

§ 54.15 Instrument grading.

■ 15. Revise § 54.16 to read as follows:

§ 54.16 Marking of products.

All products examined for class and grade under the official standards, or the immediate containers and the shipping containers, shall be stamped, branded, or otherwise marked with an appropriate official identification. Except as otherwise directed by the Director, such markings will not be required when an applicant desires only an official memorandum. The marking of products, or their containers, as required by this section shall be done by official graders or under their immediate supervision.

§ 54.15 Instrument grading.

■ 16. Revise § 54.17 to read as follows:

§ 54.17 Official identifications.

(a) A shield enclosing the letters "USDA" and identification letters assigned to the grader performing the service, as shown in Figure 1 to paragraph (a) of this section, constitutes a form of official identification under the regulations for preliminary grade of carcasses. This form of official identification may also be used to determine the final quality grade of carcasses; one stamp equates to "USDA Select" or "USDA Good"; two stamps placed together vertically equates to "USDA Choice"; and three stamps placed together vertically equates to "USDA Prime."

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Figure 1 to Paragraph (a). Preliminary Grademark.

(b) A shield enclosing the letters "USDA," as shown in Figure 2 to paragraph (b) of this section, with the appropriate quality grade designation "Prime," "Choice," "Select," "Good," "Standard," "Commercial," "Utility," "Cutter," "Canner," or "Cull," as provided in the United States Standards for Grades of Carcass Beef, the United

States Standards for Grades of Veal and Calf Carcasses, and the United States Standards for Grades of Lamb, Yearling Mutton, and Mutton Carcasses; and accompanied by the class designation "Bullock," "Veal," "Calf," "Lamb," "Yearling Mutton," or "Mutton," constitutes a form of official identification under the regulations to

show the quality grade, and where necessary, the class, under said standards, of steer, heifer, and cow beef, veal, calf, lamb, yearling mutton, and mutton. The identification letters assigned to the grader performing the service will appear underneath and outside of the shield.



Figure 2 to paragraph (b). Official Quality Grademark and/or Official Class Designation Mark.

(c) A shield enclosing the letters “USDA” and the words “Yield Grade,” as in Figure 3 to paragraph (c) of this section, with the appropriate yield grade designation “1,” “2,” “3,” “4,” or “5” as provided in the United States Standards for Grades of Carcass Beef

and the United States Standards for Grades of Lamb, Yearling Mutton, and Mutton Carcasses, constitutes a form of official identification under the regulations to show the yield grade under said standards. When yield graded, bull and bullock carcasses will

be identified with the class designation “Bull” and “Bullock,” respectively. The identification letters assigned to the grader performing the service will appear underneath and outside of the shield.



Figure 3 to paragraph (c). Official Yield Grademark.

(d) For combined quality and yield grade identification purposes only, a shield enclosing the letters “US” on one side and “DA” on the other, with the appropriate yield grade designation number “1,” “2,” “3,” “4,” or “5,” and with the appropriate quality grade

designation of “Prime,” “Choice,” “Select,” “Good,” “Standard,” “Commercial,” “Utility,” “Cutter,” “Canner,” or “Cull,” as shown in Figure 4 to paragraph (d) of this section, constitutes a form of official identification under the regulations to

show the quality and yield grade under said standards. The identification letters assigned to the grader performing the service will appear underneath and outside of the shield.



Figure 4 to paragraph (d). Official Combined Quality and Yield Grademark.

(e) Under the regulations, for yield grade identification purposes only, a shield enclosing the letters "US" on one side and "DA" on the other, and with the appropriate yield grade designation

number "1," "2," "3," "4," or "5," as shown in Figure 5 to paragraph (e) of this section, constitutes a form of official identification under the regulations to show the yield grade

under said standards. The identification letters assigned to the grader performing the service will appear underneath and outside of the shield.



Figure 5 to paragraph (e). Official Yield Grade Identification Mark.

(f) For quality grade identification only, a shield enclosing the letters "US" on one side and "DA" on the other with the appropriate quality grade designation of "Prime," "Choice," "Select," "Good," "Standard,"

"Commercial," "Utility," "Cutter," "Canner," or "Cull," as shown in Figure 6 to paragraph (f) of this section, constitutes a form of official identification under the regulations to show the yield grade under said

standards. The identification letters assigned to the grader performing the service will appear underneath and outside of the shield.

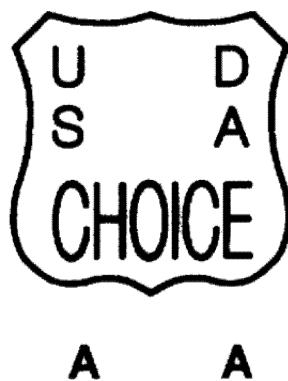


Figure 6 to paragraph (f). Official Quality Grade Identification Mark.

(g) As shown in Figure 7 to paragraph (g) of this section, a shield enclosing the letters "USDA" with the appropriate grade designation "1," "2," "3," "4," or

"Utility," as provided in the Official United States Standards for Grades of Pork Carcasses, constitutes a form of official identification under the

regulations to show the grade under said standards of barrow, gilt, and sow pork carcasses.



Figure 7 to paragraph (g). Official Grade Designation for Pork Carcasses

(h) The following constitute forms of official identification under the

regulations to show compliance of products:



Figure 8 to paragraph (h). USDA Product Control Mark.



Figure 9 to paragraph (h). USDA Accepted As Specified Mark.

(i) Figure 10 to paragraph (i) of this section, constitutes official

identification to show quality system certification.



Figure 10 to paragraph (i). USDA Process Verified Shield.

(j) Figure 11 to paragraph (j) of this section, constitutes official identification to show that products produced under USDA AMS supervision that meet specified requirements may carry the “USDA Certified” statement and/or “USDA Certified” shield, so long as each is used in direct association with a clear description of the standard or other requirement(s) to which the product claims to be certified.

(1) The “USDA Certified” shield must replicate the form and design of the example in Figure 11 and must be printed legibly and conspicuously:

(i) On a white background, with the term “USDA” in white overlaying a blue upper third of the shield and the term “Certified” in black overlaying a white middle third of the shield, with no terms in the red lower third of the shield; or

(ii) On a white or transparent background with a black trimmed shield, with the term “USDA” in white overlaying a black upper third of the shield and the term “Certified” in black overlaying the white or transparent remaining two-thirds of the shield.

(2) Use of the “USDA Certified” statement and the “USDA Certified” shield shall be approved in writing by the Director prior to use by an applicant.



Figure 11 to paragraph (j). USDA Certified Mark.

(k) Figure 12 to paragraph (k) of this section, constitutes official identification to show product or services produced under an approved USDA Further Processing Certification Program (FPCP):

(1) Products produced under an approved USDA FPCP may use the “USDA Further Processing Certification Program” statement and the “USDA Further Processing Certification Program” shield; and

(2) The USDA Further Processing Certification Program shield must replicate the form and design of the example in Figure 12 to paragraph (k) of this section and must be printed legibly and conspicuously:

(i) On a white background, with the term “USDA” in white overlaying a blue upper third of the shield and the terms “USDA Further Processing Certification Program” in black overlaying a white middle third of the shield, with no terms in the red lower third of the shield; or

(ii) On a white or transparent background with a black trimmed shield, with the term “USDA” in white overlaying a black upper third of the shield and the terms “USDA Further Processing Certification Program” in black overlaying the white or

transparent remaining two-thirds of the shield.

(3) Use of the “USDA Further Processing Certification Program” statement and the “USDA Further Processing Certification Program” shield shall be approved in writing by the Director prior to use by an applicant.

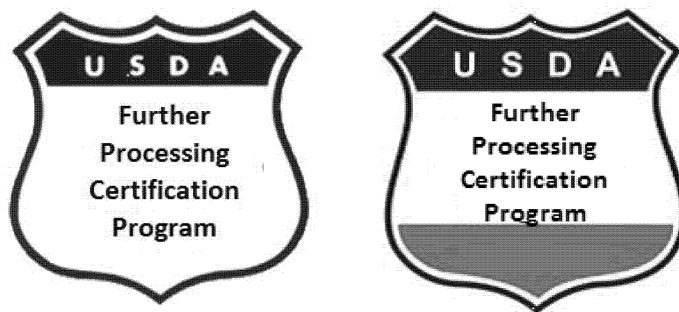


Figure 12 to paragraph (k). USDA Further Processing Certification Program Mark.

BILLING CODE 3410-02-C

(1)(1) One device used by official graders is the LP-36 Form, a rectangular, serially numbered, red tag on which a shield encloses the words “USDA Hold.” This device constitutes a form of official identification under the regulations for meat and meat products.

(2) Official graders and supervisors of grading may use “USDA Hold” tags or other methods and devices as approved by the Administrator for the identification and control of meat and meat products that are not in compliance with the regulations or are held pending the results of an examination. Any such meat or meat product identified shall not be used, moved, or altered in any manner; nor shall official control identification be removed, without the expressed permission of an authorized representative of the USDA.

■ 17. Revise § 54.18 to read as follows:

§ 54.18 Custody of identification devices.

(a) All identification devices used in marking products or their containers, including those indicating compliance with approved specifications, shall be kept in the custody of the Branch, and accurate records shall be kept by the Branch of all such devices. Such devices shall be distributed only to persons authorized by the Department, who will keep the devices in their possession or control at all times.

Subpart A—[Amended]

■ 18. Remove undesignated center heading “Appeal Service”.

■ 19. Revise § 54.19 to read as follows:

§ 54.19 Appeal of a grading service decision.

Appeal service is a redetermination of the class, grade, other quality, or compliance of product when the applicant for the appeal service formally challenges the correctness of the original determination.

(a) *Authority to request appeal service.* A request for appeal service with respect to any product may be made by any person who is financially interested in the product when that person disagrees with the original determination as to class, grade, other quality, or compliance of the product as shown by the markings on the product or its containers, or as stated in the applicable official memorandum.

(b) *Requesting appeal service.* A request for appeal service shall be filed with the Chief. The request shall state the reasons for appeal and may be accompanied by a copy of any previous official report, or any other information that the applicant may have received regarding the product at the time of the original service. Such request may be made orally (including by telephone) or in writing (including by email). If made orally, the person receiving the request may require that it be confirmed in writing.

(c) *Determining original service from appeal service.* Examination requested to determine the class, grade, other quality, or compliance of a product that has been altered or has undergone a material change since the original service, or examination of product requested for the purpose of obtaining an official memorandum and not

involving any question as to the correctness of the original service for the product involved, shall be considered equivalent to original service and not appeal service.

(d) *Not eligible for appeal service.* Grade determinations cannot be appealed for any lot or product consisting of less than 10 similar units or carcasses. Moreover, appeal service will not be furnished with respect to product that has been altered or has undergone any material change since the original service.

(e) *Withdrawal of appeal service.* A request for appeal service may be withdrawn by the applicant at any time before the appeal service has been performed; however, the applicant is responsible for payment of any expenses incurred by the Branch towards providing the appeal service prior to withdrawal.

(f) *Denial or withdrawal of appeal service.* A request for appeal service may be rejected or such service may be otherwise denied to or withdrawn from any person, without a hearing, in accordance with the procedure set forth in § 54.11(b), if it appears that the person or product involved is not eligible for appeal service under § 54.19(a) and (b), or that the identity of the product has been lost; or for any of the causes set forth in § 54.11(b). Appeal service may also be denied to, or withdrawn from, any person in any case under § 54.11(a).

(g) *Who performs appeal service.* Appeal service shall be performed by the National Meat Supervisor or his or her designee.

(h) *Appeal service report.* Immediately after appeal service has been performed for any products, a report shall be prepared and issued referring specifically to the original findings and stating the class, grade, other quality, or compliance of the products as shown by the appeal service.

■ 20. Revise § 54.20 to read as follows:

§ 54.20 Exemptions.

Any exemption to the regulations must be approved by the Director. Exemptions may include but are not limited to:

(a) Grading the meat of animals in other than carcass form if the class, grade, and other quality attributes may be determined under the applicable official standards.

(b) Grading in an establishment other than where the animal was slaughtered or initially chilled if the class, grade, and other quality attributes can be determined under the applicable official standards, and if the identity of the carcasses can be maintained.

(c) If the Branch is unable to provide grading service in a timely manner and the meat can be identified in conformance with the official standards.

(d) Grading in the establishment other than where the hide is removed, provided the meat can be identified in conformance with the official standards.

(e) Grading imported carcasses, provided:

(1) The imported carcass is marked so that the name of the country of origin is conspicuous to the USDA grader. The mark of foreign origin shall be imprinted by roller brand, handstamp, tag, or other approved method.

(2) The imprints of the mark of foreign origin have been submitted to the Chief for the determination of compliance with these regulations prior to use on meats offered for Federal grading.

(3) The applicant notifies the official grader performing the service whenever imported carcasses are offered for grading.

(f) For good cause and provided that the meat can be identified in conformance with the official standards and procedures.

§ § 54.21–54.26 [Removed and reserved]

■ 21. Remove and reserve §§ 54.21 through 54.26.

§ 54.30 [Removed and reserved]

■ 22. Remove and reserve § 54.30.

■ 23. Revise § 54.31 to read as follows:

§ 54.31 OMB control number.

The information collection and recordkeeping requirements of this part

have been approved by OMB under 44 U.S.C. Chapter 35 and have been assigned OMB Control Number 0581–0128.

Dated: September 6, 2019.

Bruce Summers,
Administrator.

[FR Doc. 2019–19707 Filed 9–13–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0324; Product Identifier 2019–NM–031–AD; Amendment 39–19726; AD 2019–17–06]

RIN 2120–AA64

Airworthiness Directives; Fokker Services B.V. Airplanes

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

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Fokker Services B.V. Model F28 Mark 0070 and 0100 airplanes. This AD was prompted by reports of cracks on certain nose landing gear (NLG) turning tubes resulting from incorrectly applied repairs. This AD requires removing the affected parts and replacing them with serviceable parts. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective October 21, 2019.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of October 21, 2019.

ADDRESSES: For Fokker service information identified in this final rule, contact Fokker Services B.V., Technical Services Dept., P.O. Box 1357, 2130 EL Hoofddorp, the Netherlands; telephone +31 (0)88–6280–350; fax +31 (0)88–6280–111; email technicalservices@fokker.com; internet <http://www.myfokkerfleet.com>. For Safran service information identified in this final rule, contact Safran Landing Systems, One Carbon Way, Walton, KY 41094; telephone (859) 525–8583; fax (859) 485–8827; internet <https://www.safran-landing-systems.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.

It is also available on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2019–0324.

Examining the AD Docket

You may examine the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2019–0324; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: 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:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Fokker Services B.V. Model F28 Mark 0070 and 0100 airplanes. The NPRM published in the **Federal Register** on May 14, 2019 (84 FR 21270). The NPRM was prompted by reports of cracks on certain NLG turning tubes resulting from incorrectly applied repairs. The NPRM proposed to require removing the affected parts and replacing them with serviceable parts.

The FAA is issuing this AD to address cracking of NLG turning tubes, which could lead to NLG turning tube failure, possibly resulting in damage to the airplane and injury to occupants.

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019–0037, dated February 19, 2019 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for all Fokker Services B.V. Model F28 Mark 0070 and 0100 airplanes. The MCAI states:

Occurrences have been reported of finding cracks on certain NLG turning tubes. The subsequent investigation results revealed that the cracks initiated from an area that is sensitive to fatigue cracking, which had been subject to incorrectly applied repairs.

This condition, if not detected and corrected, could lead to NLG turning tube

failure, possibly resulting in damage to the aeroplane and injury to occupants.
To address this potential unsafe condition, Fokker Services published the SB [service bulletin] to provide replacement instructions, referring to SLS [Safran Landing Systems] SB F100–32–117 for in-shop inspection.

For the reasons described above, this [EASA] AD requires removal from service of the affected part and replacement with a serviceable part.

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–2019–0324.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The FAA received no

comments on the NPRM or on the determination of the cost to the public.

Conclusion

The FAA reviewed the relevant data and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. The FAA has determined that these minor changes:

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

Related Service Information Under 1 CFR Part 51

Fokker Services B.V. has issued Fokker Service Bulletin SBF100–32–

171, dated November 27, 2018. This service information describes procedures for removing and replacing affected NLG turning tubes.

Safran Landing Systems has issued Safran Service Bulletin F100–32–117, dated July 30, 2018. This service information describes procedures for a magnetic particle or eddy current inspection of NLG turning tubes.

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.

Costs of Compliance

The FAA estimates that this AD affects 4 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
9 work-hours × \$85 per hour = \$765	\$1,282	\$2,047	\$8,188

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 transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

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

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

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) 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.

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2019–17–06 Fokker Services B.V.: Amendment 39–19726; Docket No. FAA–2019–0324; Product Identifier 2019–NM–031–AD.

(a) Effective Date

This AD is effective October 21, 2019.

(b) Affected ADs

None.

(c) Applicability

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

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing gear.

(e) Reason

This AD was prompted by reports of cracks on certain nose landing gear (NLG) turning tubes resulting from incorrectly applied repairs. The FAA is issuing this AD to address cracking of NLG turning tubes, which could lead to NLG turning tube failure, possibly resulting in damage to the airplane and injury to occupants.

(f) Compliance

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

(g) Definitions

- (1) An affected part is an NLG turning tube assembly having part number (P/N) 201456200, 201071202, 201071240, or

201071241 installed on an NLG unit having a part number identified in Safran Service Bulletin F100-32-117, dated July 30, 2018.

(2) A serviceable part is an affected part that is new or that, before installation, has passed an inspection (no cracks found, having the correct radius), in accordance with the Accomplishment Instructions of Safran Service Bulletin F100-32-117, dated July 30, 2018.

(h) Replacement

Within 22,000 flight cycles after the effective date of this AD: Replace the affected parts, with serviceable parts, in accordance with the Accomplishment Instructions of Fokker Service Bulletin SBF100-32-171, dated November 27, 2018.

(i) Parts Installation Limitation

As of the effective date of this AD, no person may install, on any airplane, an affected part, unless it is a serviceable part.

(j) No Reporting Requirement

Although Safran Service Bulletin F100-32-117, dated July 30, 2018, specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(k) 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 (l)(2) of this AD. Information may be emailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

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

(l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2019-0037, dated February 19, 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-2019-0324.

(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.

(m) Material Incorporated by Reference

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

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

(i) Fokker Service Bulletin SBF100-32-171, dated November 27, 2018.

(ii) Safran Service Bulletin F100-32-117, dated July 30, 2018.

(3) For Fokker service information identified in this final rule, contact Fokker Services B.V., Technical Services Dept., P.O. Box 1357, 2130 EL Hoofddorp, the Netherlands; telephone +31 (0)88-6280-350; fax +31 (0)88-6280-111; email technicalservices@fokker.com; internet <http://www.myfokkerfleet.com>. For Safran service information identified in this final rule, contact Safran Landing Systems, One Carbon Way, Walton, KY, 41094; telephone (859) 525-8583; fax (859) 485-8827; internet <http://www.safran-landing-systems.com>.

(4) 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.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Des Moines, Washington, on August 22, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019-19912 Filed 9-13-19; 8:45 am]

BILLING CODE 4910-13-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA-HQ-SFUND-1983-0002; FRL-9999-31-Region 9]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the MGM Brakes Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) Region 9 announces the deletion of the MGM Brakes Superfund Site (Site) located in Cloverdale, Sonoma County, California, from the National Priorities List (NPL). The NPL,

promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the State of California, through the Department of Toxic Substances Control, have determined that all appropriate response actions under CERCLA have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: This action is effective September 16, 2019.

ADDRESSES: *Docket:* EPA has established a docket for this action under Docket Identification No. EPA-HQ-SFUND-1983-0002. All documents in the docket are listed on the <http://www.regulations.gov> website. Although listed in the index, some information is not publicly available, *i.e.*, Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the site information repositories. Locations, contacts, phone numbers and viewing hours are:

U.S. Environmental Protection Agency, Region 9, Regional Records Center, 75 Hawthorne Street, Room 3110, San Francisco, CA 94105, (415) 947-8717, Monday-Thursday: 9:00 a.m.-12:00 p.m., 1:00 p.m.-4:00 p.m., Or:

Sonoma County Library, Headquarters, 6135 State Farm Drive, Rohnert Park, California, (707) 545-0831, *Call for hours of operation*

FOR FURTHER INFORMATION CONTACT:

Olivia Trombadore, Remedial Project Manager, U.S. Environmental Protection Agency, Region 9, SFD-9-2, 75 Hawthorne St., San Francisco, CA 94105, (415) 972-3973, trombadore.olivia@epa.gov.

SUPPLEMENTARY INFORMATION: The site to be deleted from the NPL is: MGM Brakes Superfund Site, Cloverdale, Sonoma County, California. A Notice of Intent to Delete for this Site was published in the **Federal Register** (84 FR 28259) on June 18, 2019.

The closing date for comments on the Notice of Intent to Delete was July 18, 2019. No public comments were received, and EPA still believes that this deletion action is appropriate.

EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Deletion from the NPL does not preclude further remedial action. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system. Deletion of a site from the NPL does not affect responsible party liability in the unlikely event that future conditions warrant further actions.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: August 16, 2019.

Deborah Jordan,

Acting Regional Administrator, Region 9.

For reasons set out in the preamble, 40 CFR part 300 is amended as follows:

PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

- 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Appendix B to Part 300—[Amended]

- 2. Table 1 of Appendix B to part 300 is amended by removing the entry for “CA, MGM Brakes, Cloverdale”.

[FR Doc. 2019–19672 Filed 9–13–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 180117042–8884–02]

RIN 0648–XT018

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

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

ACTION: Temporary rule; quota transfer and closure.

SUMMARY: NMFS transfers 60 metric tons (mt) of Atlantic bluefin tuna (BFT) quota from the Reserve category to the September 2019 General category subquota period and closes the General category fishery until the General category reopens on October 1, 2019. The quota transfer is intended to provide additional fishing opportunities based on consideration of the regulatory determination criteria regarding inseason adjustments and applies to Atlantic tunas General category (commercial) permitted vessels and Highly Migratory Species (HMS) Charter/Headboat category permitted vessels with a commercial sale endorsement when fishing commercially for BFT. Given that the adjusted quota is projected to be caught quickly, the closure is being filed simultaneously to prevent overharvest of the adjusted General category September 2019 BFT subquota.

DATES: The quota transfer is effective September 11, 2019, through September 30, 2019. The closure is effective 11:30 p.m., local time, September 13, 2019, through September 30, 2019.

FOR FURTHER INFORMATION CONTACT: Sarah McLaughlin, 978–281–9260, or Larry Redd, 301–420–8503.

SUPPLEMENTARY INFORMATION:

Regulations implemented under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) among the various domestic fishing categories, per the allocations established in the 2006 Consolidated Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (71 FR 58058, October 2, 2006) and amendments. NMFS is required under ATCA and the Magnuson-Stevens Act to provide U.S. fishing vessels with a reasonable opportunity to harvest the ICCAT-recommended quota.

NMFS is required, under regulations at § 635.28(a)(1), to file a closure notice for publication with the Office of the Federal Register when a BFT quota is reached or is projected to be reached. On and after the effective date and time of such notification, for the remainder of the fishing year or for a specified period as indicated in the notification, retaining, possessing, or landing BFT

under that quota category is prohibited until the opening of the subsequent quota period or until such date as specified in the notice.

The current baseline General and Reserve category quotas are 555.7 mt and 29.5 mt, respectively. See § 635.27(a). Each of the General category time periods (January, June through August, September, October through November, and December) is allocated a “subquota” or portion of the annual General category quota. The baseline subquotas for each time period are as follows: 29.5 mt for January; 277.9 mt for June through August; 147.3 mt for September; 72.2 mt for October through November; and 28.9 mt for December. Any unused General category quota rolls forward within the fishing year, which coincides with the calendar year, from one time period to the next, and is available for use in subsequent time periods. To date for 2019, NMFS has taken five actions that resulted in adjustments to the Reserve category, leaving 225.3 mt of quota currently available (84 FR 3724, February 13, 2019; 84 FR 6701, February 28, 2019; 84 FR 35340, July 23, 2019; and 84 FR 47440, September 10, 2019).

Transfer of 60 mt From the Reserve Category to the General Category

Under § 635.27(a)(9), NMFS has the authority to transfer quota among fishing categories or subcategories, after considering regulatory determination criteria provided under § 635.27(a)(8). NMFS has considered all of the relevant determination criteria and their applicability to this inseason quota transfer. These considerations include, but are not limited to, the following:

Regarding the usefulness of information obtained from catches in the particular category for biological sampling and monitoring of the status of the stock (§ 635.27(a)(8)(i)), biological samples collected from BFT landed by General category fishermen and provided by bluefin tuna dealers continue to provide valuable data for ongoing scientific studies of bluefin tuna age and growth, migration, and reproductive status. Additional opportunity to land bluefin tuna in the General category would support the continued collection of a broad range of data for these studies and for stock monitoring purposes.

NMFS also considered the catches of the General category quota to date and the likelihood of closure of that segment of the fishery if no adjustment is made (§ 635.27(a)(8)(ii) and (ix)). As of September 10, 2019, the General category landed 134.8 mt. This represents 92 percent of the baseline

September subquota (147.3 mt). At the time of drafting of this inseason action, the General category subquota has not yet been exceeded, and commercial-sized bluefin tuna remain available in the areas where General category permitted vessels operate at this time of year. Transferring 60 mt of quota from the Reserve category would result in 207.3 mt being available for the September 2019 subquota period, thus effectively providing limited additional opportunities to harvest the U.S. bluefin tuna quota while avoiding exceeding it. Given the lag between initiation of an inseason action and its implementation, however, this notice also closes the fishery, as NMFS anticipates the transferred quota will be caught quickly.

Regarding the projected ability of the vessels fishing under the particular category quota (here, the General category) to harvest the additional amount of BFT before the end of the fishing year (§ 635.27(a)(8)(iii)), NMFS anticipates that all of the 60 mt of quota will be used by September 13, based on current figures and the amount of quota being transferred, but this is also subject to weather conditions and bluefin tuna availability. In the unlikely event that any of this quota is unused by September 30, such quota will roll forward to the next subperiod within the calendar year (*i.e.*, the October through November period), and NMFS anticipates that it would be used before the end of the fishing year.

NMFS also considered the estimated amounts by which quotas for other gear categories of the fishery might be exceeded (§ 635.27(a)(8)(iv)) and the ability to account for all 2019 landings and dead discards. In the last several years, total U.S. BFT landings have been below the available U.S. quota such that the United States has carried forward the maximum amount of underharvest allowed by ICCAT from one year to the next. NMFS will need to account for 2019 landings and dead discards within the adjusted U.S. quota, consistent with ICCAT recommendations, and anticipates having sufficient quota to do that, even with the 60 mt transfer to the General category for the September fishery. NMFS anticipates that General category participants in all areas and time periods will have opportunities to harvest the General category quota in 2019, through active inseason management such as the timing of quota transfers, as practicable. Thus, this quota transfer would allow fishermen to take advantage of the availability of fish on the fishing grounds to the extent consistent with the available amount of transferrable quota and other management objectives, while avoiding

quota exceedance. NMFS also considered the effects of the adjustment on the BFT stock and the effects of the transfer on accomplishing the objectives of the FMP (§ 635.27(a)(8)(v) and (vi)). This transfer would be consistent with the current quotas, which were established and analyzed in the 2018 BFT quota final rule (83 FR 51391, October 11, 2018), and with objectives of the 2006 Consolidated HMS FMP and amendments and is not expected to negatively impact stock health or to affect the stock in ways not already analyzed in those documents. Another principal consideration is the objective of providing opportunities to harvest the full annual U.S. BFT quota without exceeding it based on the goals of the 2006 Consolidated HMS FMP and amendments, including to achieve optimum yield on a continuing basis and to optimize the ability of all permit categories to harvest their full BFT quota allocations (related to § 635.27(a)(8)(x)). Specific to the General category, this includes providing opportunity equitably across all time periods.

Based on the considerations above, NMFS is transferring 60 mt of the available 225.3 mt of Reserve category quota to the General category for the September 2019 fishery, resulting in a subquota of 207.3 mt for the September 2019 fishery and 165.3 mt in the Reserve category.

Closure of the September 2019 General Category Fishery

Based on the best available bluefin tuna General category landings information (*i.e.*, 134.8 mt landed as of September 10, 2019) as well as average catch rates and anticipated fishing conditions, NMFS projects that the General category September subquota of 207.3 mt, as adjusted in this action, will be reached by September 13, 2019, and that the fishery should be closed to avoid exceedance of the adjusted quota. Through this action, we are closing the General category bluefin tuna fishery effective 11:30 p.m., September 13, 2019, through September 30, 2019. The fishery will reopen on October 1, 2019, with a baseline quota of 72.2 mt available for the October through November time period. Therefore, retaining, possessing, or landing large medium or giant BFT by persons aboard vessels permitted in the Atlantic tunas General and HMS Charter/Headboat categories must cease at 11:30 p.m. local time on September 13, 2019. The General category will reopen automatically on October 1, 2019, for the October through November 2019 subquota period. This action applies to

those vessels permitted in the General category, as well as to those HMS Charter/Headboat permitted vessels with a commercial sale endorsement when fishing commercially for BFT fishing commercially for BFT. For information regarding the HMS Charter/Headboat commercial sale endorsement, see 82 FR 57543, December 6, 2017. The intent of this closure is to prevent overharvest of the available General category September BFT subquota.

Fishermen may catch and release (or tag and release) BFT of all sizes, subject to the requirements of the catch-and-release and tag-and-release programs at § 635.26. All BFT that are released must be handled in a manner that will maximize their survival, and without removing the fish from the water, consistent with requirements at § 635.21(a)(1). For additional information on safe handling, see the "Careful Catch and Release" brochure available at www.nmfs.noaa.gov/sfa/hms/.

Monitoring and Reporting

NMFS will continue to monitor the BFT fishery closely. Dealers are required to submit landing reports within 24 hours of a dealer receiving BFT. Late reporting by dealers compromises NMFS' ability to timely implement actions such as quota and retention limit adjustment, as well as closures, and may result in enforcement actions. Additionally, and separate from the dealer reporting requirement, General and HMS Charter/Headboat category vessel owners are required to report the catch of all BFT retained or discarded dead within 24 hours of the landing(s) or end of each trip, by accessing hmspermits.noaa.gov, using the HMS Catch Reporting app, or calling (888) 872-8862 (Monday through Friday from 8 a.m. until 4:30 p.m.).

Depending on the level of fishing effort and catch rates of BFT, NMFS may determine that additional action (*e.g.*, quota adjustment, daily retention limit adjustment, or closure) is necessary to ensure available subquotas are not exceeded or to enhance scientific data collection from, and fishing opportunities in, all geographic areas. If needed, subsequent adjustments will be published in the **Federal Register**. In addition, fishermen may call the Atlantic Tunas Information Line at (978) 281-9260, or access hmspermits.noaa.gov, for updates on quota monitoring and inseason adjustments.

Classification

The Assistant Administrator for NMFS (AA) finds that it is impracticable

and contrary to the public interest to provide prior notice of, and an opportunity for public comment on, this action for the following reasons:

The regulations implementing the 2006 Consolidated HMS FMP and amendments provide for inseason quota transfers and fishery closures to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. These fisheries are currently underway and the currently available quota for the subcategory is projected to be reached shortly. Affording prior notice and

opportunity for public comment to implement the quota transfer is impracticable and contrary to the public interest as such a delay would likely result in exceedance of the General category September fishery subquota or earlier closure of the fishery while fish are available on the fishing grounds. Subquota exceedance may result in the need to reduce quota for the General category later in the year and thus could affect later fishing opportunities. Therefore, the AA finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment. For all of the above reasons,

there also is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

This action is being taken under §§ 635.27(a)(9) and 635.28(a)(1), and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: September 11, 2019.

Jennifer M. Wallace,

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

[FR Doc. 2019–19989 Filed 9–11–19; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 84, No. 179

Monday, September 16, 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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2019-0698; Product Identifier 2019-NM-109-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) 2017-19-04 and AD 2014-16-26, which apply to certain Dassault Aviation Model FALCON 900EX airplanes. Those ADs require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive maintenance requirements and/or airworthiness limitations. Since the FAA issued AD 2017-19-04 and AD 2014-16-26, the FAA 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 October 31, 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 <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 202-493-2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201-440-6700; internet <http://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 <http://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0698; 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-2019-0698; Product Identifier 2019-NM-109-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 <http://www.regulations.gov>, including any personal information you provide. The FAA will also post a report summarizing each substantive verbal

contact received about this proposed AD.

Discussion

The FAA issued AD 2017-19-04, Amendment 39-19034 (82 FR 43163, September 14, 2017) (“AD 2017-19-04”), for certain Dassault Aviation Model FALCON 900EX airplanes. AD 2017-19-04 requires revising the existing maintenance or inspection program, as applicable, to incorporate more restrictive airworthiness limitations. AD 2017-19-04 resulted from a determination that more restrictive airworthiness limitations or more restrictive maintenance requirements and/or airworthiness limitations are necessary. The FAA issued AD 2017-19-04 to address reduced structural integrity of the airplane. AD 2017-19-04 specifies that accomplishing the actions required by that AD would terminate the requirements of AD 2014-16-26, Amendment 39-17950 (79 FR 51077, August 27, 2014) (“AD 2014-16-26”), but it did not supersede AD 2014-16-26. In addition, AD 2014-16-26 specifies that accomplishing paragraph (g) of that AD would terminate the requirements of paragraph (g)(1) of AD 2010-26-05, Amendment 39-16544 (75 FR 79952, December 21, 2010); for Dassault Aviation Model FALCON 900EX airplanes, serial numbers 1 through 96 inclusive, and serial numbers 98 through 119 inclusive. This terminating provision of certain requirements of AD 2010-26-05 is included in this proposed AD.

This AD proposes to supersede AD 2017-19-04 and AD 2014-16-26, but does not propose to supersede AD 2010-26-05.

Actions Since AD 2017-19-04 and AD 2014-16-26 Were Issued

Since AD 2017-19-04 and AD 2014-16-26 were 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 2019-0133, dated June 11, 2019 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Dassault Aviation Model FALCON 900EX airplanes. The MCAI states:

The airworthiness limitations for Falcon 900EX aeroplanes, which are approved by EASA, are currently defined and published in Dassault Falcon 900EX AMM [Airplane Maintenance Manual], Chapter 5–40. These instructions have been identified as mandatory for continued airworthiness.

Failure to accomplish these instructions could result in an unsafe condition.

EASA previously issued AD 2016–0128 (which corresponds to FAA AD 2017–19–04), requiring the actions described in Dassault Falcon 900EX AMM Chapter 5–40 (DGT113874) at Revision 14.

Since that [EASA] AD was issued, Dassault published Revisions 15 and 16 of Dassault Falcon 900EX AMM Chapter 5–40 (DGT113874). Revision 16 contains new and/or more restrictive maintenance tasks.

For the reason described above, this [EASA] AD retains the requirements of EASA AD 2016–0128, which is superseded, and requires accomplishment of the actions specified in the ALS [airworthiness limitations section], as defined in this [EASA] AD.

You may examine the MCAI in the AD docket on the internet at <http://www.regulations.gov> by searching for and locating FAA–2019–0698.

Related Service Information Under 14 CFR Part 51

Dassault Aviation has issued Chapter 5–40, Airworthiness Limitations, Revision 16, dated September 2018, of the Dassault FALCON 900EX Maintenance Manual. This service information describes procedures, maintenance tasks, and airworthiness limitations specified in the Airworthiness Limitations section of the AMM.

This proposed AD would also require Chapter 5–40, Airworthiness Limitations, Revision 14, dated November 2015, of the FALCON 900EX Maintenance Manual, which the Director of the Federal Register approved for incorporation by reference as of October 19, 2017 (82 FR 43163, September 14, 2017).

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 a bilateral agreement with the State of Design Authority, the FAA has 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 2017–19–04. This proposed AD would require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. This proposed AD would also retain the terminating provisions of AD 2014–16–26, related to AD 2010–26–05.

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 100 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 2017–19–04 to be \$7,650 (90 work-hours × \$85 per work-hour).

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency 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. Therefore, 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

■ a. Removing Airworthiness Directive (AD) 2014–16–26, Amendment 39–17950 (79 FR 51077, August 27, 2014); and AD 2017–19–04, Amendment 39–19034 (82 FR 43163, September 14, 2017); and

■ b. Adding the following new AD:

Dassault Aviation: Docket No. FAA–2019–0698; Product Identifier 2019–NM–109–AD.

(a) Comments Due Date

The FAA must receive comments by October 31, 2019.

(b) Affected ADs

(1) This AD replaces AD 2014–16–26, Amendment 39–17950 (79 FR 51077, August 27, 2014) (“AD 2014–16–26”); and AD 2017–19–04, Amendment 39–19034 (82 FR 43163, September 14, 2017) (“AD 2017–19–04”).

(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 FALCON 900EX airplanes, certificated in any category, serial numbers 1 through 96 inclusive, and serial numbers 98 through 119 inclusive, certificated in any category.

(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 reduced structural integrity of the airplane.

(f) Compliance

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

(g) Retained Revision of Maintenance or Inspection Program, With No Changes

This paragraph restates the requirements of paragraph (g) of AD 2017–19–04, with no changes. Within 90 days after October 19, 2017 (the effective date of AD 2017–19–04), revise the maintenance or inspection program, as applicable, to incorporate the information specified in Chapter 5–40, Airworthiness Limitations, Revision 14, dated November 2015, of the FALCON 900EX Maintenance Manual. The initial compliance time for accomplishing the actions specified in Chapter 5–40, Airworthiness Limitations, Revision 14, dated November 2015, of the FALCON 900EX Maintenance Manual, is within the applicable times specified in the maintenance manual, or 90 days after October 19, 2017, whichever occurs later, except as provided by paragraphs (g)(1) through (4) of this AD.

(1) The term “LDG” in the “First Inspection” column of any table in the service information means total airplane landings.

(2) The term “FH” in the “First Inspection” column of any table in the service information means total flight hours.

(3) The term “FC” in the “First Inspection” column of any table in the service information means total flight cycles.

(4) The term “M” in the “First Inspection” column of any table in the service information means months.

(h) Retained No Alternative Actions and Intervals, With New Exception

This paragraph restates the requirement specified in paragraph (h) of AD 2017–19–04, 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 or 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, Airworthiness Limitations, Revision 16, dated September 2018, of the Dassault FALCON 900EX Maintenance Manual. The initial compliance time for accomplishing the actions specified in Chapter 5–40, Airworthiness Limitations, Revision 16, dated September 2018, is within the applicable times specified in the maintenance manual, or 90 days after the effective date of this AD, whichever occurs later, except as provided by paragraphs (i)(1) through (4) of this AD.

(1) The term “LDG” in the “First Inspection” column of any table in the service information means total airplane landings.

(2) The term “FH” in the “First Inspection” column of any table in the service information means total flight hours.

(3) The term “FC” in the “First Inspection” column of any table in the service information means total flight cycles.

(4) The term “M” in the “First Inspection” column of any table in the service information means months since the date of issuance of the original airworthiness certificate or the date of issuance of the original export certificate of airworthiness.

(j) 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 and 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 FALCON 900EX airplanes, serial numbers 1 through 96

inclusive, and serial numbers 98 through 119 inclusive.

(l) Other FAA AD Provisions

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

(2) *Contacting the Manufacturer:* 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 2019–0133, dated June 11, 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–2019–0698.

(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 <http://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 September 9, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–19914 Filed 9–13–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA-2019-0651; Airspace
Docket No. 19-AGL-24]

RIN 2120-AA66

**Proposed Amendment of Class E
Airspace; Tomahawk, WI**

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking
(NPRM).

SUMMARY: This action proposes to amend the Class E airspace extending upward from 700 feet above the surface at Tomahawk Regional Airport, Tomahawk, WI. The FAA is proposing this action as the result of an airspace review requested by the Airspace Policy Group. The geographic coordinates of the airport would also be updated to coincide with the FAA's aeronautical database. Airspace redesign is necessary for the safety and management of instrument flight rules (IFR) operations at this airport.

DATES: Comments must be received on or before October 31, 2019.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366-9826, or (800) 647-5527. You must identify FAA Docket No. FAA-2019-0651; Airspace Docket No. 19-AGL-24, at the beginning of your comments. You may also submit comments through the internet at <http://www.regulations.gov>. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order 7400.11D, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11D at NARA, email fedreg.legal@nara.gov or go to [https://](https://www.archives.gov/federal-register/cfr/ibr-locations.html)

www.archives.gov/federal-register/cfr/ibr-locations.html.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT:

Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222-5711.

SUPPLEMENTARY INFORMATION:**Authority for This Rulemaking**

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Tomahawk Regional Airport, Tomahawk, WI, to support IFR operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA-2019-0651; Airspace Docket No. 19-AGL-24." The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action

on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at <http://www.regulations.gov>. Recently published rulemaking documents can also be accessed through the FAA's web page at http://www.faa.gov/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

**Availability and Summary of
Documents for Incorporation by
Reference**

This document proposes to amend FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019. FAA Order 7400.11D is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by amending the Class E airspace extending upward from 700 feet above the surface to of the Tomahawk Regional Airport, Tomahawk, WI, by adding an extension 2 miles each side of the 090° bearing from the airport extending from the 6.4-mile radius to 9.4 miles east of the airport; adding an extension 2 miles each side of the 270° bearing from the airport extending from the 6.4-mile radius to 9 miles west of the airport; and updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is necessary due to an airspace review requested by the Airspace Policy Group.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11D, dated August 8, 2019, and effective September 15, 2019, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, “Environmental Impacts: Policies and Procedures” prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and

effective September 15, 2019, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL WI E5 Tomahawk, WI [Amended]

Tomahawk Regional Airport, WI
(Lat. 45°28'10" N, long. 89°48'18" W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Tomahawk Regional Airport, and within 2 miles each side of the 090° bearing from the airport extending from the 6.4-mile radius to 9.4 miles east the airport, and within 2 miles each side of the 270° bearing extending from the 6.4-mile radius to 9 miles west of the airport.

Issued in Fort Worth, Texas, on September 9, 2019.

Steve Szukala,

*Acting Manager, Operations Support Group,
ATO Central Service Center.*

[FR Doc. 2019–19884 Filed 9–13–19; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 281 and 282

[EPA–R04–UST–2019–0310; FRL–9998–86–Region 4]

Georgia: Proposed Approval and Incorporation by Reference of State Underground Storage Tank Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Pursuant to the Resource Conservation and Recovery Act (RCRA or Act), the Environmental Protection Agency (EPA) is proposing, subject to public comment, to approve revisions to the underground storage tank (UST) program submitted by the State of Georgia (Georgia or State). The EPA has reviewed Georgia’s revisions and is proposing to determine that these revisions satisfy all requirements needed for program approval. In addition, the EPA is proposing to codify EPA’s approval of Georgia’s revised UST program and to incorporate by reference those provisions of the State statutes and regulations the EPA has determined, subject to public comment, meet the requirements for approval. The EPA seeks public comment prior to taking final action.

DATES: Comments must be received by October 16, 2019.

ADDRESSES: Submit your comments, identified by docket number EPA–R04–

UST–2019–0310, at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from <https://www.regulations.gov>. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e., on the web, cloud, or other file sharing system). For additional submission methods, 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>.

All documents in the docket are listed on the <https://www.regulations.gov> website. Publicly available docket materials are also available in hard copy at the Underground Storage Tanks and Data Management Section in the Land, Chemicals and Redevelopment Division, U.S. Environmental Protection Agency, Region 4, Atlanta Federal Center, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office’s official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Aaryn Jones, RCRA Programs and Cleanup Branch, Land, Chemicals and Redevelopment Division, U.S. Environmental Protection Agency, Region 4, Atlanta Federal Center, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960; Phone number: (404) 562–8969; email address: jones.aaryn@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Proposed Approval of Revisions to Georgia’s Underground Storage Tank (UST) Program

A. Why are revisions to state UST programs necessary?

States that have received final approval from the EPA under RCRA section 9004(b) of RCRA, 42 U.S.C. 6991c(b), must maintain a UST program that is no less stringent than the federal

program. When the EPA makes revisions to the regulations that govern the UST program, states must revise their programs to comply with the updated regulations and submit these revisions to the EPA for approval. Most commonly, states must change their programs because of changes to the EPA's regulations in 40 Code of Federal Regulations (CFR) part 280. States can also initiate changes on their own to their UST programs and these changes must then be approved by the EPA.

B. What decision is the EPA proposing to make in this rule?

On August 8, 2018, in accordance with 40 CFR 281.51(a), Georgia submitted a complete program revision application (State Application) seeking approval of changes to its UST program. The program revisions requested in the State Application correspond to the EPA final rule published on July 15, 2015 (80 FR 41566), which revised the 1988 UST regulations and the 1988 state program approval (SPA) regulations (2015 Federal Revisions). As required by 40 CFR 281.20, the State Application contains the following: A transmittal letter from the Governor requesting approval; a description of the program and operating procedures; a demonstration of the State's procedures to ensure adequate enforcement; a Memorandum of Agreement outlining the roles and responsibilities of the EPA and the implementing agency; a statement of certification from the Attorney General; and copies of all relevant State statutes and regulations. The EPA has reviewed the State Application and is proposing to determine that the revisions to Georgia's UST program are no less stringent than the corresponding federal requirements in subpart C of 40 CFR part 281, and that the Georgia program continues to provide adequate enforcement of compliance. Therefore, the EPA is proposing to grant Georgia final approval to operate its UST program with the revisions described in the State Application, and as outlined below in Section I.F. The Environmental Protection Division (EPD) of the Georgia Department of Natural Resources (DNR) is the lead implementing agency for the UST program in Georgia.

C. What is the effect of this proposed approval on the regulated community?

Section 9004(b) of RCRA, 42 U.S.C. 6991c(b), as amended, allows the EPA to approve state UST programs to operate in lieu of the federal program. If Georgia is approved for the changes described in the State Application, these changes will become part of the approved State

UST program, and therefore will be federally enforceable. Georgia will continue to have primary enforcement authority and responsibility for its State UST program. This action does not impose additional requirements on the regulated community because the regulations being proposed for approval by this rule are already in effect in the State of Georgia, and are not changed by this proposed action. This action merely proposes to approve the existing State regulations as meeting the revised federal requirements and rendering them federally enforceable.

D. What happens if the EPA receives comments that oppose this action?

The EPA will evaluate any comments received on this proposed action and will make a final decision on approval or disapproval of the UST program revisions contained in the State Application. The EPA's decision will be published in the **Federal Register**. You may not have another opportunity to comment. If you want to comment on this proposed action, you must do so at this time.

E. For what has Georgia previously been approved?

Effective July 9, 1991, the EPA granted final approval for Georgia to administer the State UST program in lieu of the federal UST program (56 FR 21603, May 10, 1991). Effective March 4, 1996, the EPA codified the provisions of the approved Georgia program that are part of the UST program under subtitle I of RCRA, and therefore are subject to the EPA's corrective action, inspection, and enforcement authorities under RCRA sections 9003(h), 9005 and 9006, 42 U.S.C. 6991b(h), 6991d and 6991e, and other applicable statutory and regulatory provisions (61 FR 4224, February 5, 1996).

F. What changes is the EPA proposing to approve with this action and what standards do we use for review?

In order to be approved, each state program revision application must meet the general requirements in 40 CFR 281.11 (General Requirements), and the specific requirements in 40 CFR part 281, subpart B (Components of a Program Application), subpart C (Criteria for No Less Stringent), and subpart D (Adequate Enforcement of Compliance).

As more fully described below, the State has made changes to its approved UST program to reflect the 2015 Federal Revisions. These changes are included in the Georgia UST Rules at Ga. Comp. R. & Regs. 391–3–15, as amended, effective November 6, 2017. The EPA is

proposing to approve the State's changes because they are no less stringent than the federal UST program, and because the revised Georgia UST program will continue to provide for adequate enforcement of compliance as required by 40 CFR 281.11(b) and part 281, subparts C and D, after this approval.

The Georgia EPD continues to be the lead implementing agency for the UST program in Georgia. The EPD continues to have broad statutory and regulatory authority to regulate the installation, operation, maintenance, and closure of USTs, as well as UST releases, under the Georgia Underground Storage Tank Act (GUSTA), Official Code of Georgia Annotated (O.C.G.A.) section 12–13–1 (2017), and the Ga. Comp. R. & Regs. 391–3–15 (2017).

As part of the State Application, the Georgia Attorney General has identified the following specific authorities for compliance monitoring, required pursuant to 40 CFR 281.40: GUSTA, O.C.G.A. sections 12–13–6(a)(3), 12–13–8(a), and 12–13–14(b); and Ga. Comp. R. & Regs. r. 391–3–15–.01(2) and 391–3–15–.08.

As part of the State Application, the Georgia Attorney General has identified the following specific authorities for enforcement response, required pursuant to 40 CFR 281.41: GUSTA, O.C.G.A. sections 12–13–15 and 12–13–19(b) and (c); and Ga. Comp. R. & Regs. r. 391–3–15–.14.

As part of the State Application, the Georgia Attorney General has identified the following specific authorities enabling public participation in the State enforcement process, required pursuant to 40 CFR 281.42: O.C.G.A. sections 12–2–2, 50–13–14, 12–13–15, 9–11–24, 12–13–6(a)(8), 12–13–16, and 12–13–21; and Ga. Comp. R. & Regs. r. 391–1–2–.14(2) and 391–3–15–.09. Further, through a Memorandum of Agreement between the State of Georgia and the EPA, effective October 12, 2018, the State maintains procedures for receiving and ensuring proper consideration of information about violations submitted by the public and will not object to public participation in administrative or civil enforcement actions. As required pursuant to 40 CFR 281.43, through the Memorandum of Agreement between the State and the EPA, the State agrees to furnish the EPA, upon request, any information in State files obtained or used in the administration of the State program.

To qualify for final approval, revisions to a state's UST program must be “no less stringent” than the 2015 Federal Revisions. In the 2015 Federal Revisions, the EPA addressed UST

systems deferred in the 1988 UST regulations, and added, among other things: New operation and maintenance requirements; secondary containment requirements for new and replaced tanks and piping; operator training requirements; and a requirement to ensure UST system compatibility before storing certain biofuel blends. In addition, the EPA removed past deferrals for emergency generator tanks, field constructed tanks, and airport hydrant systems. Georgia incorporates all the required 2015 Federal Revisions at Ga. Comp. R. & Regs. 391–3–15. Specifically, Georgia has amended its Georgia UST Rules to incorporate by reference (into the Georgia regulations) the requirements of 40 CFR part 280, including the requirements added by the 2015 Federal Revisions.

As part of the State Application, and as described above, the Georgia Attorney General has certified that the State regulations provide for adequate enforcement of compliance and meet the “no less stringent” criteria in 40 CFR part 281, subparts C and D. The EPA is relying on this certification, in addition to the analysis submitted by the State, in proposing to approve the State’s changes.

G. Where are the revised State rules different from the federal rules?

Broader in Scope Provisions

Where a state program has provisions that are broader in scope than required by federal law, these provisions are not part of the federally-approved program and are not federally enforceable, in accordance with 40 CFR 281.12(a)(3)(ii). The following State statutory and regulatory requirements are considered broader in scope than the federal and are therefore not part of federally approved State UST program:

Statutory Broader in Scope Provisions

- O.C.G.A. section 12–13–9(f)–(i) establishes the Georgia Underground Storage Tank (GUST) Fund to take emergency action, take preventive or corrective action, and provide compensation for third-party liabilities.
- O.C.G.A. section 12–13–10 requires that an environmental assurance fee be paid by any potential claimant to the GUST Fund.
- O.C.G.A. section 12–13–11(b) through (e) pertain to the use of the GUST Fund to perform corrective action.
- O.C.G.A. section 12–13–13(e) requires owners and operators of a UST in use or capable of being used to provide an annual UST notification.
- O.C.G.A. section 12–13–18(a) requires owners and operators of USTs

to maintain proof that all petroleum stored in such tank was subjected to the environmental fee imposed in O.C.G.A. section 12–13–10.

Regulatory Broader in Scope Provisions

- Ga. Comp. R. & Regs. r. 391–3–15–.05(4) requires an annual registration of USTs and an annual UST Registration Certificate.
- Ga. Comp. R. & Regs. r. 391–3–15–.09(5) requires that owners or operators may transport or provide for transportation of petroleum-contaminated soils only to permitted storage, treatment or disposal facilities and must designate any receiving facility in the corrective action plan.
- Ga. Comp. R. & Regs. r. 391–3–15–.09(7) allows owners and operators conducting corrective action with funds other than the GUST Fund to remediate soil and groundwater to a more stringent objective than those found in Ga. Comp. R. & Regs. r. 391–3–15–.09(4).
- Ga. Comp. R. & Regs. r. 391–3–15–.13 describes the requirements for owner/operator participation in the GUST Fund, including payment of an Environmental Assurance Fee (EAF) to EPD per gallon of petroleum products imported into Georgia.

More Stringent Provisions

When an approved state program includes requirements that are considered more stringent than those required by federal law, the more stringent requirements become part of the federally approved program in accordance with 40 CFR 281.12(a)(3)(i).

The following State regulatory requirements are considered more stringent than the federal program, and on approval, they will become part of the federally-approved State UST program and therefore federally enforceable:

- With respect to the definition of “replaced” found at 40 CFR 280.12, under Ga. Comp. R. & Regs. r. 391–3–15–.03(1)(n), Georgia defines “replace” when referring to piping to mean the removal and replacement of 25% or more of the existing piping.
- With respect to recordkeeping requirements found at 40 CFR 280.34 and 40 CFR 280.45, under Ga. Comp. R. & Regs. r. 391–3–15–.06(2) and 391–3–15–.07(2), Georgia requires records to be maintained for a minimum period of 36 months.
- With respect to release response and corrective action requirements found at 40 CFR part 280, subpart F, the GUST Rule is more stringent as follows:
 - (1) Under Ga. Comp. R. & Regs. r. 391–3–15–.09(2), Georgia requires that a Corrective Action Plan—Part A be

stamped or sealed by a Georgia registered Professional Engineer or Professional Geologist, and submitted in lieu of the initial abatement report, the initial site characterization report, and the free product removal report, as referenced by 40 CFR 280.62(b), 280.63(b), and 280.64(d), respectively, and must be submitted within 60 days after the release confirmation.

(2) Under Ga. Comp. R. & Regs. r. 391–3–15–.09(3), Georgia requires that a Corrective Action Plan—Part B be submitted when certain surface water, groundwater, or soil contamination levels are exceeded, or when the State otherwise determines on a site-specific basis that a Corrective Action Plan—Part B is necessary.

(3) Under Ga. Comp. R. & Regs. r. 391–3–15–.09(4), Georgia requires that if a Corrective Action Plan—Part B is necessary, the full extent of groundwater and surface water contamination must be delineated, and certain corrective action objectives must be proposed and implemented upon approval by the State.

(4) Under Ga. Comp. R. & Regs. r. 391–3–15–.09(6), Georgia requires that the owner or operator certify completion of corrective action in the completion report.

(5) Under Ga. Comp. R. & Reg. r. 391–3–15–.09(8), Georgia requires that determinations of petroleum concentrations in soil or groundwater be performed in conformity with specified methods.

(6) Under Ga. Comp. R. & Regs. r. 391–15–.10, Georgia specifies cleanup levels for releases from hazardous substance USTs.

- With respect to closure requirements found at 40 CFR 280.72, under Ga. Comp. R. & Regs. r. 391–15–.11(3), Georgia requires that owners submit an EPD UST closure report within 45 days of permanently closing a UST.

- With respect to operator training requirements found at 40 CFR 280.244, under Ga. Comp. R. & Regs. r. 391–3–15–.16, Georgia requires owners and operators to complete operator training once every seven years.

II. Codification

A. What is codification?

Codification is the process of placing citations and references to a state’s statutes and regulations that comprise a state’s approved UST program into the Code of Federal Regulations (CFR). The EPA codifies its approval of state programs in 40 CFR part 282 and incorporates by reference state statutes and regulations that the EPA can

enforce, after the approval is final, under sections 9005 and 9006 of RCRA, and any other applicable statutory provisions. The incorporation by reference of EPA-approved state programs in the CFR should substantially enhance the public's ability to discern the status of the approved state UST program and state requirements that can be federally enforced. This effort provides clear notice to the public of the scope of the approved program in each state.

B. What is the history of codification of Georgia's UST program?

In 1996, the EPA incorporated by reference and codified Georgia's approved UST program at 40 CFR 282.60 (61 FR 4224, February 5, 1996). Through this action, the EPA is proposing to amend 40 CFR 282.60 to incorporate by reference and codify Georgia's revised UST program.

C. What codification decisions is the EPA proposing in this rule?

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference of the relevant Georgia UST program, including the revisions made to the program based on the 2015 Federal Revisions. In accordance with the requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference Georgia's statutes and regulations as described in the amendments to 40 CFR part 282 set forth below. These documents are available through <https://www.regulations.gov> and at the EPA Region 4 office (see the **ADDRESSES** section of this preamble for more information). This proposed codification reflects the State UST program that would be in effect at the time the EPA's approved revisions to the Georgia UST program addressed in this proposed rule become final, subject to the receipt of public comments.

Specifically, in Section 282.60(d)(1)(i), the EPA is proposing to incorporate by reference the Georgia-approved UST program. Section 282.60(d)(1)(ii) identifies the State's statutes and regulations that are part of the approved State program, although not incorporated by reference for enforcement purposes. Section 282.60(d)(2) through (d)(5) reference the Attorney General's Statement, Demonstration of Adequate Enforcement Procedures, the Program Description, and the Memorandum of Agreement, which are part of the State Application and proposed for approval as part of the UST program under subtitle I of RCRA.

D. What is the effect of the EPA's codification of the federally approved Georgia UST program on enforcement?

The EPA retains the authority under sections 9003(h), 9005, and 9006 of subtitle I of RCRA, 42 U.S.C. 6991b(h), 6991d, and 6991e, and other applicable statutory and regulatory provisions, to undertake corrective action, inspections, and enforcement actions, and to issue orders in approved states. If the EPA determines it will take such actions in Georgia, the EPA will rely on federal sanctions, federal inspection authorities, and other federal procedures rather than the State analogs. Therefore, the EPA is not incorporating by reference Georgia's procedural and enforcement authorities, although they are listed in 40 CFR 282.60(d)(1)(ii).

E. What State provisions are not part of the codification?

As discussed in Section I.G. above, some provisions of the State's UST program are not part of the federally approved State program because they are "broader in scope" than the federal UST program. 40 CFR 281.12(a)(3)(ii) states that, where an approved state program has provisions that are broader in scope than the federal program, those provisions are not a part of the federally approved program. As a result, State provisions which are "broader in scope" than the federal program are not incorporated by reference for purposes of enforcement in part 282. In addition, provisions that are external to the State UST program approval requirements, but included in the State Application, are also being excluded from incorporation by reference in part 282. For reference and clarity, 40 CFR 282.60(d)(1)(iii) lists the Georgia statutory and regulatory provisions which are "broader in scope" than the federal program and external to state UST program approval requirements. These provisions are, therefore, not part of the approved program that the EPA is proposing to codify. Although these provisions cannot be enforced by the EPA, the State will continue to implement and enforce such provisions under State law.

III. Statutory and Executive Order (E.O.) Reviews

The EPA's proposed actions merely approve and codify Georgia's revised UST program requirements pursuant to RCRA section 9004, and do not impose additional requirements other than those imposed by State law. For that reason, these actions:

- Are not significant regulatory actions 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);

- Are not Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory actions because UST program approvals are exempted under Executive Order 12866;

- Do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

- Are 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.*);

- Do 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);

- Do not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

- Are not economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

- Are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

- Are not subject to the 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 RCRA; and

- Do 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).

- Do not 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. The rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, the EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct.

List of Subjects in 40 CFR Parts 281 and 282

Environmental protection, Administrative practice and procedure,

Petroleum, Hazardous substances, Incorporation by reference, State program approval, Underground storage tanks, and Reporting and recordkeeping requirements.

Authority: This action is issued under the authority of Sections 2002(a), 7004(b), 9004, 9005 and 9006 of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6912(a), 6974(b), 6991c, 6991d, and 6991e.

Mary S. Walker,
Regional Administrator, Region 4.

For the reasons set forth in the preamble, 40 CFR part 282 is proposed to be amended as follows:

PART 282—APPROVED UNDERGROUND STORAGE TANK PROGRAMS

■ 1. The authority citation for part 282 continues to read as follows:

Authority: 42 U.S.C. 6912, 6991c, 6991d, and 6991e.

■ 2. Revise § 282.60 to read as follows:

§ 282.60 Georgia State-Administered Program.

(a) *History of the approval of Georgia's Program.* The State of Georgia is approved to administer and enforce an underground storage tank program in lieu of the federal program under subtitle I of the Resource Conservation and Recovery Act of 1976 (RCRA), as amended, 42 U.S.C. 6991 *et seq.* The State's program, as administered by the Georgia Department of Natural Resources, Environmental Protection Division, was approved by EPA pursuant to 42 U.S.C. 6991c and part 281 of this Chapter. EPA approved the Georgia program on May 10, 1991 and it was effective on July 9, 1991. A subsequent program revision was approved by EPA and became effective on [Effective date of final rule].

(b) *Enforcement authority.* Georgia has primary responsibility for administering and enforcing its federally approved underground storage tank program. However, EPA retains the authority to exercise its corrective action, inspection, and enforcement authorities under sections 9003(h), 9005, and 9006 of subtitle I of RCRA, 42 U.S.C. 6991b(h), 6991d, and 6991e, as well as under any other applicable statutory and regulatory provisions.

(c) To retain program approval, Georgia must revise its approved program to adopt new changes to the federal subtitle I program which make it more stringent, in accordance with section 9004 of RCRA, 42 U.S.C. 6991c, and 40 CFR part 281, subpart E. If Georgia obtains approval for revised requirements pursuant to section 9004

of RCRA, 42 U.S.C. 6991c, the newly approved statutory and regulatory provisions will be added to this subpart and notice of any change will be published in the **Federal Register**.

(d) Georgia has final approval for the following elements of its underground storage tank program originally submitted to EPA and approved effective July 9, 1991, and the program revisions approved by EPA effective on [Effective date of final rule]:

(1) *State statutes and regulations.*

(i) *Incorporation by reference.* The Georgia materials cited in this paragraph, and listed in appendix A to part 282, are incorporated by reference as part of the underground storage tank program under subtitle I of RCRA, 42 U.S.C. 6991 *et seq.* The Director of the **Federal Register** approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies of the Georgia statutes that are incorporated by reference in this paragraph from LexisNexis, Attn: Official Code of Georgia Annotated, 701 East Water Street, Charlottesville, VA 22902-5389; Phone number: 1-800-833-9844; website: http://sos.ga.gov/index.php/elections/georgia_code_lexisnexis. You may obtain copies of the Georgia regulations that are incorporated by reference in this paragraph from the Administrative Procedures Division, Office of the Georgia Secretary of State, 5800 Jonesboro Road, Morrow, Georgia 30260; Phone number: (678) 364-3785; website: <http://rules.sos.ga.gov/gac/391-3-15>. You may inspect all approved material at the EPA Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303; Phone number: (404) 562-9900; or the National Archives and Records Administration (NARA). For information on the availability of the material at NARA, call (202) 741-6030 or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

(A) "Georgia Statutory Requirements Applicable to the UST Program", dated August 2018.

(B) "Georgia Regulatory Requirements Applicable to the UST Program", dated August 2018.

(ii) *Legal basis.* The EPA evaluated the following statutes and regulations which provide the legal basis for the State's implementation of the underground storage tank program, but they are not being incorporated by reference and do not replace federal authorities:

(A) *Official Code of Georgia Annotated (2017), Title 12:* "Conservation and Natural Resources," Chapter 13, "Georgia Underground

Storage Tank Act": Sections 12-13-5; 12-13-6; 12-13-8; 12-13-11(a) and (f); 12-13-14 through 12-13-17; and 12-13-19 through 12-3-22.

(B) *Rules and Regulations of the State of Georgia (November 6, 2017), Department 391:* "Rules of the Georgia Department of Natural Resources," Chapter 3, "Environmental Protection," Subject 15, "Underground Storage Tank Management": Sections 391-3-15.01(2) and 391-3-15-.14.

(iii) *Other Provisions not incorporated by reference.* The following specifically identified sections and rules applicable to the Georgia underground storage tank program that are broader in scope than the federal program or external to the state UST program approval requirements are not part of the approved program, and are not incorporated by reference herein:

(A) *Official Code of Georgia Annotated (2017), Title 12:* "Conservation and Natural Resources," Chapter 13, "Georgia Underground Storage Tank Act": Sections 12-13-3(8) and (16); 12-13-7; 12-13-9(d) through (i); 12-13-10; 12-13-11(b) through (e); 12-13-12; 12-13-13(e), and 12-13-18.

(B) *Rules and Regulations of the State of Georgia (November 6, 2017), Department 391:* "Rules of the Georgia Department of Natural Resources," Chapter 3, "Environmental Protection," Subject 15, "Underground Storage Tank Management": Sections 391-3-15-.01(1); 391-3-15-.03(1)(a), (g), (i), and (p) through (r); 391-3-15-.04; 391-3-15-.05(4); 391-3-15-.09(5) and (7); 391-15-3-.12(3); 391-3-15-.13; and 391-3-15-.15.

(2) *Statement of legal authority.* The Attorney General's Statement, signed by the Attorney General on June 12, 2018, though not incorporated by reference, is referenced as part of the approved underground storage tank program under subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

(3) *Demonstration of procedures for adequate enforcement.* The "Demonstration of Procedures for Adequate Enforcement" submitted as part of Georgia's application on August 8, 2018, though not incorporated by reference, is referenced as part of the approved underground storage tank program under subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

(4) *Program description.* The Program Description submitted as part of Georgia's application on August 8, 2018, though not incorporated by reference, is referenced as part of the approved underground storage tank program under subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

(5) *Memorandum of Agreement*. The Memorandum of Agreement between EPA Region 4 and the Georgia Environmental Protection Division, signed by EPA Regional Administrator on October 12, 2018, though not incorporated by reference, is referenced as part of the approved underground storage tank program under subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

■ 3. Appendix A to part 282 is proposed to be amended by revising the entry for Georgia to read as follows:

Appendix A to Part 282—State Requirements Incorporated by Reference in Part 282 of the Code of Federal Regulations

* * * * *

Georgia

(a) The statutory provisions include: *Official Code of Georgia Annotated (2017), Title 12: "Conservation and Natural Resources," Chapter 13, "Georgia Underground Storage Tank Act":*
Section 12–13–1 Short title.
Section 12–13–2 Public policy.
Section 12–13–3 Definitions, except (8) and (16).
Section 12–13–4 Exceptions to chapter.
Section 12–13–9 Establishing financial responsibility; claims against the guarantor; Underground Storage Tank Trust Fund, except (d) through (i).
Section 12–13–13 Notification by owner of underground storage tank, except (e).

(b) The regulatory provisions include: *Rules and Regulations of the State of Georgia (November 6, 2017), Department 391: "Rules of the Georgia Department of Natural Resources," Chapter 3, "Environmental Protection," Subject 15, "Underground Storage Tank Management":*
Section 391–3–15–.01(3) General Provisions
Section 391–3–15–.02 UST Exclusions.
Section 391–3–15–.03 Definitions, except (1)(a), (1)(g), (1)(i), and (1)(p) through and (r).
Section 391–3–15–.05 UST Systems: Design, Construction, Installation, and Notification, except (4).
Section 391–3–15–.06 General Operating Requirements.
Section 391–3–15–.07 Release Detection.
Section 391–3–15–.08 Release Reporting, Investigation, and Confirmation.
Section 391–3–15–.09 Release Response and Corrective Action for UST Systems Containing Petroleum, except (5) and (7).
Section 391–3–15–.10 Release Response and Corrective Action for UST Systems Containing Hazardous Substances.
Section 391–3–15–.11 Out-of-Service UST Systems and Closure.
Section 391–3–15–.12 Underground Storage Tanks Containing Petroleum; Financial Responsibility Requirements, except (3).
Section 391–3–15–.16 Operator Training.
Section 391–3–15–.17 Airport Hydrant Systems and Field Constructed Tanks.
(c) Copies of the Georgia statutes that are incorporated by reference are available from LexisNexis, Attn: Official Code of Georgia Annotated, 701 East Water Street, Charlottesville, VA 22902–5389; Phone

number: 1–800–833–9844; website: http://sos.ga.gov/index.php/elections/georgia_code_-_lexisnexis. Copies of the Georgia regulations that are incorporated by reference are available from the Administrative Procedures Division, Office of the Georgia Secretary of State, 5800 Jonesboro Road, Morrow, Georgia 30260; Phone number: (678) 364–3785; website: <http://rules.sos.ga.gov/gac/391-3-15>.

* * * * *
[FR Doc. 2019–19936 Filed 9–13–19; 8:45 am]
BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION
46 CFR Parts 502 and 515
[Docket No. 19–04]
RIN 3072–AC75

Hearing Procedures Governing the Denial, Revocation, or Suspension of an OTI License
Correction
In proposed rule document 2019–18742 beginning on page 45934 in the issue of Tuesday, September 3, 2019, make the following correction:
The heading should read as set forth above.

[FR Doc. C1–2019–18742 Filed 9–13–19; 8:45 am]
BILLING CODE 1301–00–D

Notices

Federal Register

Vol. 84, No. 179

Monday, September 16, 2019

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

September 11, 2019.

The Department of Agriculture has submitted the following information collection requirement(s) to Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. Comments are requested regarding: Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by October 16, 2019 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725—17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@OMB.EOP.GOV or fax (202) 395-5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250-7602. Copies of the submission(s) may be obtained by calling (202) 720-8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs

potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Utilities Service

Title: The Rural eConnectivity Pilot Program (ReConnect Program).

OMB Control Number: 0572-0152.

Summary of Collection: Pursuant to the Pilot Program authorization in the Consolidated Appropriations Act, 2018, Public Law 115-141, 779 (2018), RUS is to conduct a pilot broadband program under the RE Act. Under Section 601(d)(1) of the RE Act applicants are required to submit an application for loans and loan guarantees containing the information that the Secretary shall require, and that the project meet the minimum level of broadband in the service area. Section 601(d)(8) sets out the all of the reporting requirements, and the Pilot Program specifically requires that the Section 601(d)(8) reporting requirements be followed. Additionally, Section 601(h) requires that the Secretary ensure the security of any loan or guarantee.

Need And Use of the Information: On March 23, 2018, Congress passed the Consolidated Appropriations Act 2018 (the FY2018 Appropriations) (Pub. L. 115-141) which established a broadband loan and grant pilot program, the Rural eConnectivity Pilot Program (hereinafter the ReConnect Program). One of the essential goals of the ReConnect Program is to expand broadband service to rural areas without sufficient access to broadband, defined as 10 megabits per second (Mbps) downstream and 1 Mbps upstream. For this purpose, Congress provided RUS with \$600 million and expanded its existing authority to make loans and grants. Loans and grants are limited to the costs of the construction, improvement, and acquisition of facilities and equipment for broadband service in eligible communities. The FY2018 Appropriations also authorized technical assistance to assist the agency in expanding needed service to the most rural communities.

Description of Respondents: Not-for-profit institutions; Business or other for-profit; State, local, and Tribal governments.

Number of Respondents: 500.

Frequency Of Responses: Reporting: On occasion.

Total Burden Hours: 156,090.

Kimble Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2019-19915 Filed 9-13-19; 8:45 am]

BILLING CODE 3410-15-P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

September 11, 2019.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Comments are requested regarding: whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by October 16, 2019 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), OIRA_Submission@omb.eop.gov or fax (202) 395-5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250-7602. Copies of the submission(s) may be obtained by calling (202) 720-8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it

displays a currently valid OMB control number.

Food and Nutrition Service

Title: Federal Collection Methods for Supplemental Nutrition Assistance Program Recipient Claims.

OMB Control Number: 0584–0446.

Summary of Collection: Section 13(b) of the Food and Nutrition Act of 2008 (The Act) and Supplemental Nutrition Assistance Program (SNAP) regulations at 7 CFR 273.18 require State agencies to refer delinquent debtors for SNAP benefit over-issuance to the U.S. Department of Treasury for collection. The Debt Collection Improvement Act of 1996 (DCIA), 31 U.S.C. 3701, *et seq.*, requires these debts to be referred to Treasury for collection when they are 180 days or more delinquent. Through the Treasury Offset Program (TOP), 31 CFR part 285, payments such as Federal income tax refunds, Federal salaries and other Federal payments payable to these delinquent debtors will be offset and the amount applied to the delinquent debt.

Need and Use of the Information: The information collected is used by individuals or households to obtain due process before debts are referred to TOP for offset. State agencies will use the collected information to provide due process to individuals/households; to add and maintain debts in TOP; to request addresses; and to certify to Treasury the accuracy and legality of debts that are submitted to TOP. Without the information, compliance with the DCIA would not be possible and departmental participation in TOP would be jeopardized.

Description of Respondents: 53 State, Local, or Tribal Government; 305,020 Individual or households.

Number of Respondents: 305,073.

Frequency of Responses: Recordkeeping; Reporting: On occasion; Annually.

Total Burden Hours: 56,653.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2019–19956 Filed 9–13–19; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2019–0055]

Notice of Availability of an Evaluation of the Highly Pathogenic Avian Influenza and Newcastle Disease Status of Romania

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that we are proposing to recognize Romania as being free of highly pathogenic avian influenza and Newcastle disease. This proposed recognition is based on a risk evaluation we have prepared in connection with this action, which we are making available for review and comment.

DATES: We will consider all comments that we receive on or before November 15, 2019.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0055>.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2019–0055, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0055> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Mr. Javier Vargas, Senior Staff Officer, Regionalization Evaluation Services, Veterinary Services, APHIS, 4700 River Road, Unit 38, Riverdale, MD 20737–1231; (301) 851–3316; javier.vargas@usda.gov.

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation of certain animals and animal products into the United States in order to prevent the introduction of various animal diseases, including highly pathogenic avian influenza (HPAI) and Newcastle disease. Within

part 94, § 94.6 contains requirements governing the importation of carcasses, meat, parts or products of carcasses, and eggs (other than hatching eggs) of poultry, game birds, or other birds from regions where HPAI and Newcastle disease is considered to exist.

In accordance with § 94.6(a)(1)(i) the Animal and Plant Health Inspection Service (APHIS) maintains a list of regions in which Newcastle disease is not considered to exist. Paragraph (a)(1)(ii) states that APHIS will add a region to this list after it conducts an evaluation of the region and finds that Newcastle disease is not likely to be present in its commercial bird or poultry populations.

In accordance with § 94.6(a)(2)(i), APHIS maintains a list of regions in which HPAI is considered to exist. Paragraph (a)(2)(ii) states that APHIS will remove a region from this list only after it conducts an evaluation of the region and finds that HPAI is not likely to be present in its commercial bird or poultry populations.

The regulations in 9 CFR part 92, § 92.2, contain requirements for requesting the recognition of the animal health status of a region (as well as for the approval of the export of a particular type of animal or animal product to the United States from a foreign region). If, after review and evaluation of the information submitted in support of the request, APHIS believes the request can be safely granted, APHIS will make its evaluation available for public comment through a document published in the **Federal Register**. Following the close of the comment period, APHIS will review all comments received and will make a final determination regarding the request that will be detailed in another document published in the **Federal Register**.

The Government of Romania has requested that APHIS evaluate the HPAI and Newcastle disease status of the country. In response to Romania's request, we have prepared an evaluation, titled "APHIS Evaluation of the Highly Pathogenic Avian Influenza and Newcastle Disease Status of Romania" (May 2019). Based on this evaluation, we have determined that Romania's domestic poultry populations are currently free of both HPAI and Newcastle disease as defined in 9 CFR 94.0. APHIS acknowledges the continuing risk posed by wild birds in Romania and the European Union (EU); however, Romania's competent veterinary authority takes effective prevention and control measures minimizing the risk of introduction to commercial poultry, and these are sufficient to minimize the likelihood of

introducing HPAI and Newcastle disease into the United States via imports of species or products susceptible to these diseases. Our determination supports adding Romania to the Web-based list of regions in which Newcastle disease is not considered to exist and removing Romania from the Web-based list of regions in which HPAI is considered to exist.

APHIS also concludes that Romania meets the requirements to form part of the EU Poultry Trade Region (EUPTR), an APHIS-recognized region of the EU that meets APHIS requirements for being considered free of HPAI and Newcastle disease, and for which the importation of live birds and poultry and poultry meat and products is harmonized.

Therefore, in accordance with § 92.2(e), we are announcing the availability of our risk evaluation of the HPAI and Newcastle disease status of Romania for public review and comment.

In April 2012, APHIS prepared an environmental assessment (EA) analyzing the potential effects on the human environment from listing the 25 Member States that constituted the EU in 2006 as a region free of HPAI and Newcastle disease (collectively referred to as EUPTR). The EA has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provision of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The evaluation and EA may be viewed on the *Regulations.gov* website or in our reading room. (Instructions for accessing *Regulations.gov* and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this notice.) The documents are also available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Information submitted in support of Romania's request is available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

After reviewing any comments we receive, we will announce our decision regarding the disease status of Romania with respect to HPAI and Newcastle disease in a subsequent notice.

Authority: 7 U.S.C. 1633, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136

and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 10th day of September 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–19893 Filed 9–13–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2019–0045]

National Wildlife Services Advisory Committee; Meeting; Correction

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of meeting; correction.

SUMMARY: We are correcting an error in a notice published in the **Federal Register** on August 6, 2019, which announced a forthcoming National Wildlife Services Committee meeting. We provided an incorrect arrival time for attendees. This document corrects that error.

The meeting will still begin at 8 a.m. and end at 5 p.m. on September 18 and 19, 2019.

FOR FURTHER INFORMATION CONTACT: Ms. Carrie Joyce, Designated Federal Officer, Wildlife Services, APHIS, 4700 River Road, Unit 87, Riverdale, MD 20737; (301) 851–3999.

SUPPLEMENTARY INFORMATION:

Correction

In a notice published in the **Federal Register** on August 6, 2019, FR Doc. 2019–16758, on page 38202, third column, under **SUPPLEMENTARY INFORMATION**, third paragraph, correct the second sentence to read:

Attendees should arrive between 7:30 and 8 a.m.

Done in Washington, DC, this 10th day of September 2019.

Cikena Reid,

Committee Management Officer, USDA.

[FR Doc. 2019–19892 Filed 9–13–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Proposed New Fee Sites: The Lolo National Forest

AGENCY: Forest Service, USDA.

ACTION: Notice of proposed new fee sites; comment request.

SUMMARY: The Lolo National Forest is proposing to charge new fees at four day-use sites, three recreation rental facilities and seven campgrounds across the Forest as described in the supplementary section of this notice.

All sites have had recent upgrades and new or improved amenities added to improve the services and recreation experiences. The Driveway Peak lookout is being moved from its current location on Priscilla Peak to a more accessible location on Driveway Peak. Fees are assessed based on the level of amenities and services provided, cost of operation and maintenance, market assessment, and public comment. Funds from these fees will be used for continued operation, maintenance and capital improvements to these recreation sites. These new fees would align the sites with other sites offering similar amenities and services. These fees are only proposed and will be determined upon further analysis and public comment.

DATES: Send any comments about these fee proposals by October 16, 2019, comments will be compiled, analyzed, and shared with the Recreation Resource Advisory Council(s). The proposed fees will become available pending a recommendation from the Resource Advisory Committee. If approved by the Regional Forester, the Forest Service will implement the new fee changes in 2020.

ADDRESSES: Written comments concerning this notice should be addressed to the Supervisor's Office: Lolo National Forest, Attn: Recreation Fee Proposals, 24 Fort Missoula Road, Missoula, MT 59804.

FOR FURTHER INFORMATION CONTACT: Kate Jerman, Public Affairs Officer, 406–329–1024 or by email at r1recfee@fs.fed.us. Information about proposed fee changes can also be found on the Lolo National Forest Fee proposal website at www.fs.usda.gov/goto/r1recfee.

SUPPLEMENTARY INFORMATION: The Federal Recreation Lands Enhancement Act (Title VII, Pub. L. 108–447) directed the Secretary of Agriculture to publish a six month advance notice in the **Federal Register** whenever new recreation fee areas are established.

Once public involvement is complete, these new fees will be reviewed by the Resource Advisory Council(s) prior to a final decision and implementation.

Specifically, the Lolo National Forest is proposing the following new fees:

- Big Hole Lookout; proposed fee of \$45 per night;
- Driveway Peak Lookout; proposed fee of \$55 per night;

- Savenac East Cottage; proposed fee of \$80 per night;
- Seeley Lake and Big Larch Day Use Areas/Boat Launches; proposed fee of \$5 per vehicle, per day; or a \$35 annual pass;
- Pattee Canyon and Seeley Creek Winter trail complexes; proposed fee of \$5 per vehicle, per day; or a \$35 annual pass;
- Big Horn, Big Nelson, Fishtrap Lake, Kreis Pond, Lake Inez, Little Joe and Siria campgrounds; proposed fee of \$10 per night, with an additional \$5 extra vehicle fee per night for more than two vehicles.
- Big Horn, Big Nelson, Fishtrap Lake, Kreis Pond, Lake Inez, Little Joe and Siria campgrounds; proposed fee of \$10 per night, with an additional \$5 extra vehicle fee per night for more than two vehicles.

Fees, paid by users of these sites and services, will help ensure that the Forest can continue maintaining and improving the sites for future generations. A market analysis of surrounding recreation sites with similar amenities indicates that the proposed fees are comparable and reasonable.

Advance reservations for the Big Hole and Driveway Peak Lookouts, and Savenac East Cottage will be available through www.recreation.gov or by calling 1-877-444-6777. The reservation service charges \$8.00 for fee reservations.

Dated: August 14, 2019.

Richard A. Cooksey,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2019-19991 Filed 9-13-19; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF COMMERCE

Census Bureau

Proposed Information Collection; Comment Request; Generic Clearance for Collection of State Administrative Records Data

AGENCY: U.S. Census Bureau, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, 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 proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: To ensure consideration, written comments must be submitted on or before November 15, 2019.

ADDRESSES: Direct all written comments to Michael Berning, Assistant Division Chief for Data Acquisition and Curation, U.S. Census Bureau, 4600 Silver Hill Road, Room 5H151, Washington, DC 20233 (or via the internet at PRAComments@doc.gov). You may also submit comments, identified by Docket Number USBC-2019-0008, to the Federal e-Rulemaking Portal: <http://www.regulations.gov>. All comments received are part of the public record. No comments will be posted to <http://www.regulations.gov> for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Michael Berning, U.S. Census Bureau, 4600 Silver Hill Road, Room 5H151, Washington, DC 20233-8400 at (301) 763-2028.

SUPPLEMENTARY INFORMATION

I. Abstract

The U.S. Census Bureau plans to request a general clearance for acquiring State administrative records in order to improve efficiency and accuracy in our data collections, and to improve measures of the population and economy. The records to be acquired are person-level program participating records that will be used to support the decennial census program as well as for research topics that includes eligibility analyses. The Census Bureau has undertaken research projects to integrate and link State administrative records with Census Bureau data from current surveys and censuses.

The Census Bureau uses the State administrative records linked with other survey and census records to conduct further research and improve operations with surveys and censuses, including 2020 Census Operations. The Census Bureau benefits from these projects by improving data quality and estimates, as well as studies of program participation over time. State data providers have benefited through access to tabulated

data and reports to better understand the demographic characteristics of program participants and to administer their programs.

II. Method of Collection

The Census Bureau will contact the State agencies to discuss how the Census Bureau might use of State administrative records. After entering into a data sharing agreement with the Census Bureau, a State agency would transfer the agreed-upon administrative records to the Census Bureau via secure File Transfer Protocol or encrypted CD-ROM or DVD-ROM.

III. Data

OMB Control Number: 0607-0995.

Form Number(s): Information will be collected in the form of a data transfer to the Census Bureau. No form will be used.

Type of Review: Regular submission.

Affected Public: State governments.

Estimated Number of Respondents: 50 states and the District of Columbia.

Estimated Time Per Response: 75 hours.

Estimated Total Annual Burden Hours: 3,825 hours.

Estimated Total Annual Cost to Public: \$80,325 (This is not the cost of respondents' time, but the indirect costs respondents may incur for such things as purchases of specialized software or hardware needed to report, or expenditures for accounting or records maintenance services required specifically by the collection.)

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. Section 6.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection;

they also will become a matter of public record.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019-19923 Filed 9-13-19; 8:45 am]

BILLING CODE 3510-07-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-489-830]

Steel Concrete Reinforcing Bar From the Republic of Turkey: Preliminary Results of Countervailing Duty Administrative Review; 2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminary determines that a producer/exporter of steel concrete reinforcing bar (rebar) from the Republic of Turkey (Turkey) received countervailable subsidies during the period of review (POR) March 1, 2017 through December 31, 2017. Interested parties are invited to comment on these preliminary results.

DATES: Applicable September 16, 2019.

FOR FURTHER INFORMATION CONTACT:

Kathryn Turlo, 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) 482-3870.

SUPPLEMENTARY INFORMATION:

Background

On September 10, 2018, Commerce published a notice of initiation of an administrative review of the countervailing duty (CVD) order on rebar from Turkey.¹ On March 28, 2019, Commerce extended the deadline for the preliminary results to September 6, 2019.² Commerce preliminarily finds that the mandatory respondent, Habas Sinai ve Tibbi Gazlar Istihsal Endustrisi A.S. (Habas),³ received countervailable

subsidies during the POR. For a complete description of the events that followed the initiation of this review, see the Preliminary Decision Memorandum.⁴ A list of topics discussed in the Preliminary Decision Memorandum is included at the appendix to this notice. The Preliminary 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 is available to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <http://enforcement.trade.gov/frn/>. The signed and electronic versions of the Preliminary Decision Memorandum are identical in content.

On January 28, 2019, Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018 through the resumption of operations on January 29, 2019.⁵ On August 7, 2019 Commerce postponed the preliminary results of this review until September 6, 2019.⁶

Scope of the Order

The merchandise covered by the order is rebar from Turkey. For a complete description of the scope, see the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each subsidy program found countervailable, we preliminarily find that there is a subsidy, *i.e.*, a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is

specific.⁷ For a full description of the methodology underlying our conclusions, see the Preliminary Decision Memorandum.

Preliminary Results of the Review

Commerce calculated an individual estimated countervailable subsidy rate for Habas, the only individually examined exporter/producer in this review, for the period March 1, 2017 through December 31, 2017, as follows:

Company	Subsidy rate <i>ad valorem</i> (percent)
Habas Sinai ve Tibbi Gazlar Istihsal Endustrisi A.S. ⁸	3.08

Assessment Rates

Consistent with section 751(a)(2)(C) of the Act, upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. We intend to issue instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

Pursuant to section 751(a)(1) of the Act, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amount indicated above for the reviewed companies, with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all other firms, we will instruct CBP to collect cash deposits at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

We will disclose to the parties in this proceeding the calculations performed in reaching the preliminary results within five days of the date of publication of this notice.⁹ Interested parties may submit written arguments

¹ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 83 FR 45596, 45606 (September 10, 2018).

² See Memorandum, "Steel Concrete Reinforcing Bar from the Republic of Turkey: Extension of Deadline for Preliminary Results in 2017 Countervailing Duty Administrative Review," dated March 28, 2019.

³ Habas is the sole Turkish rebar producer/exporter excluded from the existing CVD order on rebar from Turkey. See *Steel Concrete Reinforcing Bar from the Republic of Turkey: Countervailing Duty Order*, 79 FR 65926 (November 6, 2014) (2014 Turkey CVD Order).

⁴ See Memorandum, "Decision Memorandum for the Preliminary Results of Countervailing Duty Administrative Review: Steel Concrete Reinforcing Bar from the Republic of Turkey; 2017," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

⁵ See Memorandum to the Record from Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, "Deadlines Affected by the Partial Shutdown of the Federal Government," dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

⁶ See Memorandum, "Steel Concrete Reinforcing Bar from the Republic of Turkey: Second Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review—2017–2018," dated August 7, 2019.

⁷ See sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

⁸ This rate applies only to merchandise both produced and exported by Habas. Merchandise produced by Habas, but exported by another company, or produced by another company and exported by Habas continues to be covered by the 2014 Turkey CVD Order.

⁹ See 19 CFR 351.224(b).

(case briefs) on the preliminary results within 30 days of publication of the preliminary results, and rebuttal comments (rebuttal briefs) within five days after the time limit for filing case briefs.¹⁰ Pursuant to 19 CFR 351.309(d)(2), rebuttal briefs must be limited to issues raised in the case briefs. Parties who submit arguments are requested to submit with the argument: (1) Statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.¹¹

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request within 30 days after the date of publication of this notice.¹² Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. If Commerce receives a request for a hearing, we will inform parties of the scheduled date for the hearing, which will be held at the main Department of Commerce building at a time and location to be determined.¹³ Parties should confirm by telephone the date, time, and location of the hearing.

Parties are reminded that briefs and hearing requests are to be filed electronically using ACCESS and received successfully in their entirety by 5:00 p.m. Eastern Time on the due date.

Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act, Commerce intends to issue the final results of this administrative review, including the results of our analysis of the issues raised by parties in their comments, within 120 days after publication of these preliminary results.

Notification to Interested Parties

These preliminary results of review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213 and 351.221(b)(4).

Dated: September 6, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Subsidies Valuation Information
- V. Analysis of Programs

¹⁰ See 19 CFR 351.309(c)(1)(ii); 351.309(d)(1); and 19 CFR 351.303 (for general filing requirements).

¹¹ See 19 CFR 351.309(c)(2) and 351.309(d)(2).

¹² See 19 CFR 351.310(c).

¹³ See 19 CFR 351.310.

VIII. Conclusion

[FR Doc. 2019–19921 Filed 9–13–19; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–088, C–570–089]

Certain Steel Racks and Parts Thereof From the People's Republic of China: Amended Final Affirmative Antidumping Duty Determination and Antidumping Duty Order; and Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on affirmative final determinations by the Department of Commerce (Commerce) and the International Trade Commission (ITC), Commerce is issuing the antidumping duty (AD) and countervailing duty (CVD) orders on certain steel racks and parts thereof (steel racks) from the People's Republic of China (China). In addition, Commerce is amending its final determination of sales at less than fair value (LTFV) to correct ministerial errors.

DATES: Applicable September 16, 2019.

FOR FURTHER INFORMATION CONTACT:

Maliha Khan (AD) or Robert Galantucci (CVD), AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0895 and (202) 482–2923, respectively.

SUPPLEMENTARY INFORMATION:

Background

In accordance with sections 735(d) and 705(d) of the Tariff Act of 1930, as amended (the Act), on July 24, 2019, Commerce published its affirmative final determination of sales at LTFV¹ and its affirmative final determination that countervailable subsidies are being provided to producers and exporters of steel racks from China.²

On September 9, 2019, the ITC notified Commerce of its final affirmative determination that an industry in the United States is materially injured by reason of LTFV imports and subsidized imports of steel

racks from China, within the meaning of sections 735(b)(1)(A)(i) and 705(b)(1)(A)(i) of the Act.³

Scope of the Orders

The products covered by these orders are steel racks from China. For a complete description of the scope of the orders, see the Appendix to this notice.

Amendment to the Final Determination of Sales at LTFV

Pursuant to sections 735(e) of the Act and 19 CFR 351.224(e) and (f), Commerce is amending the *AD Final Determination* to correct two ministerial errors. A ministerial error is defined as an error in addition, subtraction, or other arithmetic function, clerical error resulting from inaccurate copying, duplication, or the like, and any other similar type of unintentional error which the Secretary considers ministerial.⁴

In the *AD Final Determination*, we made ministerial errors by including a surrogate value for brokerage and handling (B&H) expenses in our surrogate value spreadsheet and by stating that we added surrogate B&H expenses to movement expenses for material inputs when we did not do so. The record demonstrates that we intentionally did not add surrogate B&H expenses to movement expenses for material inputs. Therefore, we are amending the *AD Final Determination* to correct our misstatement regarding the addition of surrogate B&H expenses and to clarify our intention with respect to the inclusion of those expenses in the surrogate values for material inputs. First, we did not add surrogate B&H expenses to movement expenses for material inputs in the *AD Final Determination*. Our statement that we did add these expenses is incorrect. Second, our statements in the *AD Final Determination* mischaracterize our intention with respect to B&H expenses related to the movement of material inputs. Our statements indicate that we intended to add surrogate B&H expenses to movement expenses for material inputs when we did not. For further details, see the Ministerial Error Memorandum.⁵

³ See ITC September 9, 2019 letter regarding notification of final determinations (ITC Notification).

⁴ See section 735(e) of the Act; and 19 CFR 351.224(f).

⁵ See Memorandum, “Less-Than-Fair-Value Investigation of Steel Racks and Parts Thereof from the People's Republic of China: Allegation of Ministerial Errors in the Final Determination,” dated September 10, 2019 (Ministerial Error Memorandum).

AD Order

On September 9, 2019, in accordance with section 735(d) of the Act, the ITC notified Commerce of its final determination that an industry in the United States is materially injured within the meaning of section 735(b)(1)(A)(i) of the Act by reason of imports of steel racks from China that are sold in the United States at LTFV.⁶ Therefore, in accordance with section 735(c)(2) of the Act, we are issuing this AD order. Because the ITC determined that imports of steel racks from China are materially injuring a U.S. industry, unliquidated entries of such merchandise from China entered, or withdrawn from warehouse, for consumption are subject to the assessment of antidumping duties.

As a result of the ITC's final determination, in accordance with section 736(a)(1) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by Commerce, antidumping duties equal to the amount by which the normal value of the merchandise exceeds the export price or constructed export price of the subject merchandise, for all relevant entries of steel racks from China. Antidumping duties will be assessed on unliquidated entries of steel racks from China entered, or withdrawn from warehouse, for consumption on or after March 4, 2019, the date of publication of the *AD Preliminary Determination*,⁷ but antidumping duties will not be assessed on entries of subject merchandise after the expiration of the provisional measures period and before

publication in the **Federal Register** of the ITC's final injury determination, as further described below.

Continuation of Suspension of Liquidation—AD

Except as noted in the "Provisional Measures—AD" section of this notice below, in accordance with section 735(c)(1)(B) of the Act, Commerce will instruct CBP to continue to suspend liquidation on all relevant entries of steel racks from China. These instructions suspending liquidation will remain in effect until further notice.

Commerce will also instruct CBP to require cash deposits equal to the estimated weighted-average dumping margins indicated in the table below. Given that the provisional measures period has expired, as explained below, effective on the date of publication in the **Federal Register** of the notice of the ITC's final affirmative injury determination, CBP will require, at the same time as importers would normally deposit estimated duties on subject merchandise, a cash deposit equal to the estimated weighted-average dumping margins listed in the table below.⁸ The China-wide entity rate applies to all exporter-producer combinations not specifically listed.

Provisional Measures—AD

Section 733(d) of the Act states that suspension of liquidation pursuant to an affirmative preliminary determination may not remain in effect for more than four months, except where exporters representing a significant proportion of

exports of the subject merchandise request that Commerce extend the four-month period to no more than six months. At the request of exporters that account for a significant proportion of steel racks from China, Commerce extended the four-month period to six months in this proceeding. Commerce published the preliminary determination on March 4, 2019. Hence, the extended provisional measures period, beginning on the date of publication of the preliminary determination, ended on August 30, 2019.

Therefore, in accordance with section 733(d) of the Act and our practice,⁹ Commerce will instruct CBP to terminate the suspension of liquidation and to liquidate, without regard to antidumping duties, unliquidated entries of steel racks from China, entered, or withdrawn from warehouse, for consumption after August 30, 2019, the final day on which the provisional measures were in effect, until and through the day preceding the date of publication of the ITC's final affirmative injury determination in the **Federal Register**. Suspension of liquidation and the collection of cash deposits will resume on the date of publication of the ITC's final determination in the **Federal Register**.

Estimated Weighted-Average Dumping Margins

The estimated weighted-average dumping margin percentages are as follows:

Exporter	Producer	Estimated weighted-average dumping margin (percent)
Nanjing Dongsheng Shelf Manufacturing Co., Ltd	Nanjing Dongsheng Shelf Manufacturing Co., Ltd	18.06
Ateel Display Industries (Xiamen) Co., Ltd	Ateel Display Industries (Xiamen) Co., Ltd	18.06
CTC Universal (Zhangzhou) Industrial Co., Ltd	CTC Universal (Zhangzhou) Industrial Co., Ltd	18.06
David Metal Craft Manufactory Ltd	David Metal Craft Manufactory Ltd	18.06
Guangdong Wireking Housewares and Hardware Co., Ltd	Guangdong Wireking Housewares and Hardware Co., Ltd	18.06
Hebei Minmetals Co., Ltd	Hebei Wuxin Garden Products Co., Ltd	18.06
Hebei Minmetals Co., Ltd	Huanghua Xinxing Furniture Co., Ltd	18.06
Hebei Minmetals Co., Ltd	Huanghua Xingyu Hardware Products Co., Ltd	18.06
Hebei Minmetals Co., Ltd	Huangua Qingxin Hardware Products Co., Ltd	18.06
Hebei Minmetals Co., Ltd	Huangua Haixin Hardware Products Co., Ltd	18.06
Hebei Minmetals Co., Ltd	Huanghua Hualing Hardware Products Co., Ltd	18.06
i-Lift Equipment Ltd	Yuanda Storage Equipment Ltd	18.06
Jiangsu Nova Intelligent Logistics Equipment Co., Ltd	Jiangsu Nova Intelligent Logistics Equipment Co., Ltd	18.06
Johnson (Suzhou) Metal Products Co., Ltd	Johnson (Suzhou) Metal Products Co., Ltd	18.06
Master Trust (Xiamen) Import and Export Co., Ltd	Zhangzhou Hongcheng Hardware & Plastic Industry Co., Ltd	18.06
Nanjing Ironstone Storage Equipment Co., Ltd	Jiangsu Baigeng Logistics Equipments Co., Ltd	18.06

⁶ See ITC Notification.

⁷ See *Steel Racks and Parts Thereof from the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value*, 84 FR 7326 (March 4, 2019) (*AD Preliminary Determination*). In the *AD Final Determination*, we

incorrectly stated that suspension would continue from February 25, 2019. The correct date is March 4, 2019.

⁸ See section 736(a)(3) of the Act.

⁹ See *Certain Corrosion-Resistant Steel Products from India, Italy, the People's Republic of China, the Republic of Korea and Taiwan: Amended Final Affirmative Antidumping Determination for India and Taiwan, and Antidumping Duty Orders*, 81 FR 48390, 48392 (July 25, 2016).

Exporter	Producer	Estimated weighted-average dumping margin (percent)
Nanjing Kingmore Logistics Equipment Manufacturing Co., Ltd	Nanjing Kingmore Logistics Equipment Manufacturing Co., Ltd	18.06
Nanjing Kingmore Logistics Equipment Manufacturing Co., Ltd	Jiangsu Kingmore Storage Equipment Manufacturing Co., Ltd	18.06
Ningbo Beilun Songyi Warehouse Equipment Manufacturing Co., Ltd.	Ningbo Beilun Songyi Warehouse Equipment Manufacturing Co., Ltd.	18.06
Ningbo Xinguang Rack Co., Ltd	Ningbo Xinguang Rack Co., Ltd	18.06
Qingdao Rockstone Logistics Appliance Co., Ltd	Qingdao Rockstone Logistics Appliance Co., Ltd	18.06
Redman Corporation	Redman Corporation	18.06
Redman Import & Export Limited	Redman Corporation	18.06
Suzhou (China) Sunshine Hardware & Equipment Imp. & Exp. Co. Ltd.	Changzhou Tianyue Storage Equipment Co., Ltd	18.06
Suzhou (China) Sunshine Hardware & Equipment Imp. & Exp. Co. Ltd.	Ningbo Beilun Songyi Warehouse Equipment Manufacturing Co., Ltd.	18.06
Tianjin Master Logistics Equipment Co., Ltd	Tianjin Master Logistics Equipment Co., Ltd	18.06
Waken Display System Co., Ltd	CTC Universal (Zhangzhou) Industrial Co., Ltd	18.06
Xiamen Baihuide Manufacturing Co., Ltd	Xiamen Baihuide Manufacturing Co., Ltd	18.06
Xiamen Ever Glory Fixtures Co., Ltd	Fujian First Industry and Trade Co., Ltd	18.06
Xiamen Ever Glory Fixtures Co., Ltd	Fujian Ever Glory Fixtures Co., Ltd	18.06
Xiamen Ever Glory Fixtures Co., Ltd	Xiamen Ever Glory Fixtures Co., Ltd	18.06
Xiamen Golden Trust Industry & Trade Co., Ltd	Xiamen Golden Trust Industry & Trade Co., Ltd	18.06
Xiamen Kingfull Imp and Exp Co., Ltd. (d.b.a) Xiamen Kingfull Displays Co., Ltd.	Xiamen Huiyi Beauty Furniture Co., Ltd	18.06
Xiamen Kingfull Imp and Exp Co., Ltd. (d.b.a) Xiamen Kingfull Displays Co., Ltd.	Xiamen LianHong Industry and Trade Co., Ltd	18.06
Xiamen LianHong Industry and Trade Co., Ltd	Xiamen LianHong Industry and Trade Co., Ltd	18.06
Xiamen Luckyroc Industry Co., Ltd	Xiamen Luckyroc Storage Equipment Manufacture Co., Ltd	18.06
Xiamen Meitoushan Metal Products Co., Ltd	Xiamen Meitoushan Metal Products Co., Ltd	18.06
Xiamen Power Metal Display Co., Ltd	Xiamen Power Metal Display Co., Ltd	18.06
Xiamen XinHuiYuan Industrial & Trade Co., Ltd	Xiamen XinHuiYuan Industrial & Trade Co., Ltd	18.06
Xiamen Yiree Display Fixtures Co., Ltd	Xiamen Yiree Display Fixtures Co., Ltd	18.06
Zhangjiagang Better Display Co., Ltd	Zhangjiagang Better Display Co., Ltd	18.06
China-wide entity		144.50

CVD Order

On September 9, 2019, in accordance with sections 705(b)(1)(A)(i) and 705(d) of the Act, the ITC notified Commerce of its final determination that an industry in the United States is materially injured by reason of subsidized imports of steel racks from China.¹⁰ Therefore, in accordance with sections 705(c)(2) and 706 of the Act, we are issuing this CVD order.

As a result of the ITC's final affirmative determination, in accordance with section 706(a) of the Act, Commerce will direct CBP to assess, upon further instruction by Commerce, countervailing duties on unliquidated entries of steel racks from China entered, or withdrawn from

warehouse, for consumption on or after December 3, 2018, the date of publication of the *CVD Preliminary Determination*,¹¹ but will not include entries occurring after the expiration of the provisional measures period and before publication in the **Federal Register** of the ITC's final injury determination, as further described below.

Suspension of Liquidation—CVD

In accordance with section 706 of the Act, we will instruct CBP to reinstitute suspension of liquidation on all relevant entries of subject merchandise (*i.e.*, steel racks from China), effective on the date of publication of the ITC's notice of final affirmative injury determination in the **Federal Register**, and to assess, upon

further instruction by Commerce, pursuant to section 706(a)(1) of the Act, countervailing duties for each entry of the subject merchandise in an amount based on the net countervailable subsidy rate for the subject merchandise. We will also instruct CBP to require, at the same time as importers would normally deposit estimated duties on this merchandise, cash deposits for each entry of subject merchandise equal to the rates noted below.

These instructions suspending liquidation will remain in effect until further notice. The all-others rate applies to all producers or exporters not specifically listed. The estimated subsidy rates for the countervailing duty order are as follows:

Company	Subsidy rate (percent)
Designa Inc	102.23
Dongguan Baike Electronic Co., Ltd	102.23
Ezidone Display Corp. Ltd	102.23
Fenghua Huige Metal Products Co., Ltd	102.23

¹⁰ See ITC Notification.

¹¹ See *Certain Steel Racks from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination, and Alignment*

of Final Determination with Final Antidumping Duty Determination, 83 FR 62297 (December 3, 2018) (*CVD Preliminary Determination*).

Company	Subsidy rate (percent)
Formost Plastic Metal Works (Jiaxing) Co., Ltd	102.23
Jiangsu Kingmore Storage Equipment Manufacturing Co., Ltd	102.23
Nanjing Dongsheng Shelf Manufacturing Co., Ltd	1.50
Nanjing Huade Storage Equipment Manufacture Co., Ltd	102.23
Ningbo Bocheng Home Products Co., Ltd	102.23
Ningbo Joys Imp. & Exp. Co., Ltd	102.23
Ningbo Li Zhan Import & Export Co	102.23
Qingdao Haineng Hardware Products Co., Ltd	102.23
Qingdao Huatian Hand Truck Co., Ltd	102.23
Qingdao Zeal-Line Stainless Steel Products Co., Ltd	102.23
Seven Seas Furniture Industrial (Xiamen) Co., Ltd	102.23
Shijiazhuang Wells Trading & Mfg. Co., Ltd	102.23
Tangshan Apollo Energy Equipment Company	102.23
All-Others	1.50

Provisional Measures—CVD

Section 703(d) of the Act states that suspension of liquidation instructions issued pursuant to an affirmative preliminary determination may not remain in effect for more than four months. Commerce published its *CVD Preliminary Determination* on December 3, 2018. Therefore, the four-month period beginning on the date of the publication of the *Preliminary Determination* continued through April 1, 2019.

Therefore, in accordance with section 703(d) of the Act, Commerce instructed CBP to terminate the suspension of liquidation and to liquidate, without regard to countervailing duties, unliquidated entries of steel racks from China entered, or withdrawn from warehouse, for consumption on or after April 2, 2019, the date on which provisional measures expired, through the day preceding the date of publication of the ITC's final affirmative injury determinations in the **Federal Register**. Suspension of liquidation will resume on the date of publication of the ITC's final affirmative injury determinations in the **Federal Register**.

Notifications to Interested Parties

This notice constitutes the AD and CVD orders with respect to steel racks from China pursuant to sections 736(a) and 706(a) of the Act. Interested parties can find a list of orders currently in effect at <http://enforcement.trade.gov/stats/iastats1.html>.

These orders are published in accordance with sections 706(a) and 736(a) of the Act and 19 CFR 351.211(b).

Dated: September 11, 2019.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

Scope of the Orders

The merchandise covered by these orders is steel racks and parts thereof, assembled, to any extent, or unassembled, including but not limited to, vertical components (e.g., uprights, posts, or columns), horizontal or diagonal components (e.g., arms or beams), braces, frames, locking devices (e.g., end plates and beam connectors), and accessories (including, but not limited to, rails, skid channels, skid rails, drum/coil beds, fork clearance bars, pallet supports, row spacers, and wall ties).

Subject steel racks and parts thereof are made of steel, including, but not limited to, cold and/or hot-formed steel, regardless of the type of steel used to produce the components and may, or may not, include locking tabs, slots, or bolted, clamped, or welded connections. Subject steel racks have the following physical characteristics:

- (1) Each steel vertical and horizontal load bearing member (e.g., arms, beams, posts, and columns) is composed of steel that is at least 0.044 inches thick;
- (2) Each steel vertical and horizontal load bearing member (e.g., arms, beams, posts, and columns) is composed of steel that has a yield strength equal to or greater than 36,000 pounds per square inch;
- (3) The width of each steel vertical load bearing member (e.g., posts and columns) exceeds two inches; and
- (4) The overall depth of each steel roll-formed horizontal load bearing member (e.g., beams) exceeds two inches.

In the case of steel horizontal load bearing members other than roll-formed (e.g., structural beams, Z-beams, or cantilever arms), only the criteria in subparagraphs (1) and (2) apply to these horizontal load bearing members. The depth limitation in subparagraph (4) does not apply to steel horizontal load bearing members that are not roll-formed.

Steel rack components can be assembled into structures of various dimensions and configurations by welding, bolting, clipping, or with the use of devices such as clips, end plates, and beam connectors, including, but

not limited to the following configurations:

(1) Racks with upright frames perpendicular to the aisles that are independently adjustable, with positive-locking beams parallel to the aisle spanning the upright frames with braces; and (2) cantilever racks with vertical components parallel to the aisle and cantilever beams or arms connected to the vertical components perpendicular to the aisle. Steel racks may be referred to as pallet racks, storage racks, stacker racks, retail racks, pick modules, selective racks, or cantilever racks and may incorporate moving components and be referred to as pallet-flow racks, carton-flow racks, push-back racks, movable-shelf racks, drive-in racks, and drive-through racks. While steel racks may be made to ANSI MH16.1 or ANSI MH16.3 standards, all steel racks and parts thereof meeting the description set out herein are covered by the scope of these orders, whether or not produced according to a particular standard.

The scope includes all steel racks and parts thereof meeting the description above, regardless of

- (1) other dimensions, weight, or load rating;
- (2) vertical components or frame type (including structural, roll-form, or other);
- (3) horizontal support or beam/brace type (including but not limited to structural, roll-form, slotted, unslotted, Z-beam, C-beam, L-beam, step beam, and cantilever beam);
- (4) number of supports;
- (5) number of levels;
- (6) surface coating, if any (including but not limited to paint, epoxy, powder coating, zinc, or other metallic coatings);
- (7) rack shape (including but not limited to rectangular, square, corner, and cantilever);
- (8) the method by which the vertical and horizontal supports connect (including but not limited to locking tabs or slots, bolting, clamping, and welding); and
- (9) whether or not the steel rack has moving components (including but not limited to rails, wheels, rollers, tracks, channels, carts, and conveyors).

Subject merchandise includes merchandise matching the above description that has been finished or packaged in a third country. Finishing includes, but is not limited to, coating, painting, or assembly, including attaching the merchandise to another product, or any other finishing or assembly operation that would not remove the

merchandise from the scope of these orders if performed in the country of manufacture of the steel racks and parts thereof. Packaging includes packaging the merchandise with or without another product or any other packaging operation that would not remove the merchandise from the scope of these orders if performed in the country of manufacture of the steel racks and parts thereof.

Steel racks and parts thereof are included in the scope of these orders whether or not imported attached to, or included with, other parts or accessories such as wire decking, nuts, and bolts. If steel racks and parts thereof are imported attached to, or included with, such non-subject merchandise, only the steel racks and parts thereof are included in the scope.

The scope of these orders does not cover: (1) Decks, *i.e.*, shelving that sits on or fits into the horizontal supports to provide the horizontal storage surface of the steel racks; (2) wire shelving units, *i.e.*, units made from wire that incorporate both a wire deck and wire horizontal supports (taking the place of the horizontal beams and braces) into a single piece with tubular collars that slide over the posts and onto plastic sleeves snapped on the posts to create a finished unit; (3) pins, nuts, bolts, washers, and clips used as connecting devices; and (4) non-steel components.

Specifically excluded from the scope of these orders are any products covered by Commerce's existing antidumping and countervailing duty orders on boltless steel shelving units prepackaged for sale from the People's Republic of China. *See Boltless Steel Shelving Units Prepackaged for Sale from the People's Republic of China: Antidumping Duty Order*, 80 FR 63,741 (October 21, 2017); and *Boltless Steel Shelving Units Prepackaged for Sale from the People's Republic of China: Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order*, 80 FR 63,745 (October 21, 2017).

Also excluded from the scope of these orders are bulk-packed parts or components of boltless steel shelving units that were specifically excluded from the scope of the Boltless Steel Shelving Orders because such bulk-packed parts or components do not contain the steel vertical supports (*i.e.*, uprights and posts) and steel horizontal supports (*i.e.*, beams, braces) packaged together for assembly into a completed boltless steel shelving unit.

Such excluded components of boltless steel shelving are defined as:

(1) Boltless horizontal supports (beams, braces) that have each of the following characteristics: (a) A length of 95 inches or less, (b) made from steel that has a thickness of 0.068 inches or less, and (c) a weight capacity that does not exceed 2,500 lbs per pair of beams for beams that are 78" or shorter, a weight capacity that does not exceed 2,200 lbs per pair of beams for beams that are over 78" long but not longer than 90", and/or a weight capacity that does not exceed 1,800 lbs per pair of beams for beams that are longer than 90";

(2) shelf supports that mate with the aforementioned horizontal supports; and

(3) boltless vertical supports (upright welded frames and posts) that have each of

the following characteristics: (a) A length of 95 inches or less, (b) with no face that exceeds 2.90 inches wide, and (c) made from steel that has a thickness of 0.065 inches or less.

Excluded from the scope of these orders are: (1) Wall-mounted shelving and racks, defined as shelving and racks that suspend all of the load from the wall, and do not stand on, or transfer load to, the floor; (2) ceiling-mounted shelving and racks, defined as shelving and racks that suspend all of the load from the ceiling and do not stand on, or transfer load to, the floor; and (3) wall/ceiling mounted shelving and racks, defined as shelving and racks that suspend the load from the ceiling and the wall and do not stand on, or transfer load to, the floor. The addition of a wall or ceiling bracket or other device to attach otherwise subject merchandise to a wall or ceiling does not meet the terms of this exclusion.

Also excluded from the scope of these orders is scaffolding that complies with ANSI/ASSE A10.8—2011—Scaffolding Safety Requirements, CAN/CSA S269.2—M87 (Reaffirmed 2003)—Access Scaffolding for Construction Purposes, and/or Occupational Safety and Health Administration regulations at 29 CFR part 1926 subpart L—Scaffolds.

Also excluded from the scope of these orders are tubular racks such as garment racks and drying racks, *i.e.*, racks in which the load bearing vertical and horizontal steel members consist solely of: (1) Round tubes that are no more than two inches in diameter; (2) round rods that are no more than two inches in diameter; (3) other tubular shapes that have both an overall height of no more than two inches and an overall width of no more than two inches; and/or (4) wire.

Also excluded from the scope of these orders are portable tier racks. Portable tier racks must meet each of the following criteria to qualify for this exclusion:

(1) They are freestanding, portable assemblies with a fully welded base and four freely inserted and easily removable corner posts;

(2) They are assembled without the use of bolts, braces, anchors, brackets, clips, attachments, or connectors;

(3) One assembly may be stacked on top of another without applying any additional load to the product being stored on each assembly, but individual portable tier racks are not securely attached to one another to provide interaction or interdependence; and

(4) The assemblies have no mechanism (*e.g.*, a welded foot plate with bolt holes) for anchoring the assembly to the ground.

Also excluded from the scope of these orders are accessories that are independently bolted to the floor and not attached to the rack system itself, *i.e.*, column protectors, corner guards, bollards, and end row and end of aisle protectors.

Merchandise covered by these orders is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under the following subheadings: 7326.90.8688, 9403.20.0081 and 9403.90.8041. Subject merchandise may also enter under subheadings 7308.90.3000, 7308.90.6000, 7308.90.9590, and 9403.20.0090. The HTSUS subheadings are provided for convenience

and U.S. Customs purposes only. The written description of the scope is dispositive.¹²

[FR Doc. 2019–19949 Filed 9–13–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–829]

Steel Concrete Reinforcing Bar From the Republic of Turkey: Preliminary Results of Antidumping Duty Administrative Review; 2017–2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily finds that exporters of steel concrete reinforcing bar (rebar) from the Republic of Turkey (Turkey) sold subject merchandise in the United States at prices below normal value during the period of review (POR) March 7, 2017 through June 30, 2018. We invite all interested parties to comment on these preliminary results.

DATES: Applicable September 16, 2019.

FOR FURTHER INFORMATION CONTACT:

Kathryn Wallace and Thomas Dunne, 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) 482–6251 and (202) 482–2328, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce is conducting an administrative review of the antidumping duty order on rebar from Turkey in accordance with section 751(a)(1)(B) of Tariff Act of 1930, as amended (the Act).¹ On September 10, 2018, in accordance with 19 CFR 351.221(c)(1)(i), we initiated an administrative review of the *Order* covering six companies.² On October 30, 2018, Commerce selected Icdas Celik Enerji Tersane ve Ulasim Sanayi A.S. (Icdas) and Kaptan Demir Celik Endüstrisi ve Ticaret A.S. (Kaptan Demir) as the mandatory respondents

¹² See Memorandum, “Steel Racks from the People's Republic of China (A–570–088, C–570–089),” dated August 8, 2019. CBP notified Commerce that HTSUS number 9403.20.0080 was replaced with 9403.20.0081.

¹ See *Steel Concrete Reinforcing Bar from the Republic of Turkey and Japan: Amended Final Affirmative Antidumping Duty Determination for the Republic of Turkey and Antidumping Duty Orders*, 82 FR 32532 (July 14, 2017) (*Order*).

² See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 83 FR 45596 (September 10, 2018).

for this review.³ Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018 through the resumption of operations on January 29, 2019.⁴ On April 9, 2019 and August 7, 2019, Commerce postponed the preliminary results of this review.⁵ The revised deadline for the preliminary results is September 6, 2019.

Scope of the Order

The product covered by the *Order* is steel concrete reinforcing bar from Turkey. For a full description of the scope, see the Preliminary Decision Memorandum.⁶

Methodology

Commerce is conducting this review in accordance with section 751 of the Act. Export price is calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying the preliminary results, see the Preliminary Decision Memorandum. A list of topics discussed in the Preliminary Decision Memorandum is attached as an appendix to this notice.

The Preliminary 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 <https://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 Preliminary Decision Memorandum can be accessed directly

at <http://enforcement.trade.gov/frn/>. The signed and electronic versions of the Preliminary Decision Memorandum are identical in content.

Preliminary Results of This Review

As a result of this review, we calculated a preliminary weighted-average dumping margin of 0.91 percent for Kaptan Demir and 1.57 for Icdas for the POR. Commerce calculated the rate for the companies not selected for individual examination using a weighted-average of the estimated weighted-average dumping margins calculated for Icdas and Kaptan Demir and each company's publicly-ranged values for the merchandise under consideration.⁷ We preliminarily determine that the following weighted-average dumping margins exist for the period of March 7, 2017 through June 30, 2018:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Icdas Celik Enerji Tersane ve Ulasim Sanayi A.S	1.57
Kaptan Demir Celik Endüstrisi ve Ticaret A.S	0.91
Colakoglu Dis Ticaret A.S	* 1.41
Colakoglu Metalurji A.S	* 1.41
Habas Sinai ve Tibbi Gazlar Istihsal Endustrisi A.S	* 1.41
Kaptan Metal Dis Ticaret ve Nakliyat A.S	* 1.41

* This rate is the weighted-average of the estimated weighted-average dumping margins for Icdas and Kaptan Demir, using each company's publicly-ranged values for the merchandise under consideration.

Assessment Rates

Upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all

appropriate entries covered by this review. For any individually examined respondents whose weighted-average dumping margin is above *de minimis* (i.e., 0.50 percent), we will calculate importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1).⁸ We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate calculated in the final results of this review is not zero or *de minimis*. If either individually-selected respondents' weighted-average dumping margin is zero or *de minimis*, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review where applicable.

In accordance with Commerce's "automatic assessment" practice, for entries of subject merchandise during the POR produced by Kaptan Demir and Icdas for which each company did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate those entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction. We intend to issue instructions to CBP 15 days after the publication date of the final results of this review.

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the companies under review will be the rate established in the final results of this review (except, if the *ad valorem* rate is *de minimis*, then the cash deposit rate will be zero); (2) for previously reviewed or investigated companies not covered in this review, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment of this

³ See Memorandum, "Respondent Selection for the Antidumping Duty Administrative Review of Steel Concrete Reinforcing Bar from the Republic of Turkey," dated October 30, 2018.

⁴ See Memorandum to the Record from Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, "Deadlines Affected by the Partial Shutdown of the Federal Government," dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

⁵ See Memoranda, "Steel Concrete Reinforcing Bar from the Republic of Turkey—1st Administrative Review: Extension of Deadline for the Preliminary Results of the Review," and "Steel Concrete Reinforcing Bar from the Republic of Turkey: Second Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review—2017–2018," dated April 9, 2019 and August 7, 2019, respectively.

⁶ See Memorandum, "Decision Memorandum for Preliminary Results of Antidumping Duty Administrative Review: Steel Concrete Reinforcing Bar from the Republic of Turkey; 2017–2018" dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

⁷ With two respondents under examination, Commerce normally calculates (A) a weighted-average of the estimated weighted-average dumping margins calculated for the examined respondents; (B) a simple average of the estimated weighted-average dumping margins calculated for the examined respondents; and (C) a weighted-average of the estimated weighted-average dumping margins calculated for the examined respondents using each company's publicly-ranged U.S. sale quantities for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for producers and exporters not subject to individual examination. See *Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part*, 75 FR 53661, 53663 (September 1, 2010).

For a complete analysis of the data, see the Companies Not Selected for Individual Examination Calculation Memorandum.

⁸ In these preliminary results, Commerce applied the assessment rate calculation methodology adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification*, 77 FR 8101 (February 14, 2012).

proceeding in which the company was reviewed; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation, but the producer is, the cash deposit rate will be the rate established for the most recently-completed segment of this proceeding for the producer of subject merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 7.26 percent, the all-others rate established in the investigation.⁹

These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

Commerce intends to disclose its calculations and analysis performed within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties will have the opportunity to comment on the preliminary results and may submit case briefs and/or written comments at a date to be determined in a memorandum following the issuance of the preliminary results. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.¹⁰ Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this review are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. Case and rebuttal briefs should be filed using ACCESS.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically-filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; (3) whether any participant is a foreign national; and (4) a list of issues parties intend to discuss. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs.¹¹ If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue

NW, Washington, DC 20230, at a time and date to be determined.¹² Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, which will include the results of its analysis of issues raised in any briefs, within 120 days of publication of these preliminary results, pursuant to section 751(a)(3)(A) of the Act.

Notification to Importers

This notice serves as a preliminary reminder to importers 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 POR. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification to Interested Parties

The preliminary results of review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: September 6, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Companies Not Selected for Individual Examination
- V. Comparisons to Normal Value
- VI. Date of Sale
- VII. Export Price
- VIII. Normal Value
- IX. Currency Conversion
- X. Recommendation

[FR Doc. 2019-19922 Filed 9-13-19; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

Announcement of November 2019 Through April 2020 International Trade Administration Trade Missions

AGENCY: International Trade Administration, Department of Commerce.

SUMMARY: The United States Department of Commerce, International Trade Administration (ITA) is announcing five upcoming trade missions that will be recruited, organized, and implemented by ITA. These missions are:

- Additive Manufacturing Trade Mission to Europe—November 17–22, 2019.
- Envirotech Executive Service Mission to India—February 9–15, 2020.
- Asia EDGE Trade Mission to Southeast Asia—March 16–20, 2020.
- Trade Winds Indo Pacific Hong Kong & Indo Pacific Region—April 20–28, 2020.

A summary of each mission is found below. Application information and more detailed mission information, including the commercial setting and sector information, can be found at the trade mission website: <http://export.gov/trademissions>.

For each mission, recruitment will be conducted in an open and public manner, including publication in the **Federal Register**, posting on the Commerce Department trade mission calendar (<http://export.gov/trademissions>) and other internet websites, press releases to general and trade media, direct mail, broadcast fax, notices by industry trade associations and other multiplier groups, and publicity at industry meetings, symposia, conferences, and trade shows.

FOR FURTHER INFORMATION CONTACT:

Gemal Brangman, Trade Promotion Programs, Industry and Analysis, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington DC 20230, telephone (202) 482-3773.

SUPPLEMENTARY INFORMATION:

The following conditions for participation will be used for each mission:

Applicants must submit a completed and signed mission application and supplemental application materials, including adequate information on their products and/or services, primary market objectives, and goals for participation. If the Department of Commerce receives an incomplete application, the Department may either: reject the application, request additional information/clarification, or take the lack of information into account when evaluating the application. If the requisite minimum number of participants is not selected for a particular mission by the recruitment deadline, the mission may be cancelled.

Each applicant must also certify that the products and services it seeks to export through the mission are either produced in the United States, or, if not,

⁹ See Order, 82 FR at 32533.

¹⁰ See 19 CFR 351.309; see also 19 CFR 351.303 (for general filing requirements).

¹¹ See 19 CFR 351.310(c).

¹² See 19 CFR 351.310(c).

are marketed under the name of a U.S. firm and have at least fifty-one percent U.S. content by value. In the case of a trade association or organization, the applicant must certify that, for each firm or service provider to be represented by the association/organization, the products and/or services the represented firm or service provider seeks to export are either produced in the United States or, if not, marketed under the name of a U.S. firm and have at least 51% U.S. content.

A trade association/organization applicant must certify to the above for all of the companies it seeks to represent on the mission.

In addition, each applicant must:

- Certify that the products and services that it wishes to market through the mission would be in compliance with U.S. export controls and regulations;
- Certify that it has identified any matter pending before any bureau or office in the Department of Commerce;
- Certify that it has identified any pending litigation (including any administrative proceedings) to which it is a party that involves the Department of Commerce; and
- Sign and submit an agreement that it and its affiliates (1) have not and will not engage in the bribery of foreign officials in connection with a company's/participant's involvement in this mission, and (2) maintain and enforce a policy that prohibits the bribery of foreign officials.

In the case of a trade association/organization, the applicant must certify that each firm or service provider to be represented by the association/organization can make the above certifications.

The following selection criteria will be used for each mission:

Targeted mission participants are U.S. firms, services providers and trade associations/organizations providing or promoting U.S. products and services that have an interest in entering or expanding their business in the mission's destination country. The following criteria will be evaluated in selecting participants:

- Suitability of the applicant's (or in the case of a trade association/organization, represented firm's or service provider's) products or services to these markets;
- The applicant's (or in the case of a trade association/organization, represented firm's or service provider's) potential for business in the markets, including likelihood of exports resulting from the mission; and
- Consistency of the applicant's (or in the case of a trade association/

organization, represented firm's or service provider's) goals and objectives with the stated scope of the mission.

Balance of company size and location may also be considered during the review process. Referrals from a political party or partisan political group or any information, including on the application, containing references to political contributions or other partisan political activities will be excluded from the application and will not be considered during the selection process. The sender will be notified of these exclusions.

Trade Mission Participation Fees:

If and when an applicant is selected to participate on a particular mission, a payment to the Department of Commerce in the amount of the designated participation fee below is required. Upon notification of acceptance to participate, those selected have 5 business days to submit payment or the acceptance may be revoked.

Participants selected for a trade mission will be expected to pay for the cost of personal expenses, including, but not limited to, international travel, lodging, meals, transportation, communication, and incidentals, unless otherwise noted. Participants will, however, be able to take advantage of U.S. Government rates for hotel rooms. In the event that a mission is cancelled, no personal expenses paid in anticipation of a mission will be reimbursed. However, participation fees for a cancelled mission will be reimbursed to the extent they have not already been expended in anticipation of the mission.

If a visa is required to travel on a particular mission, applying for and obtaining such a visa will be the responsibility of the mission participant. Government fees and processing expenses to obtain such a visa are not included in the participation fee. However, the Department of Commerce will provide instructions to each participant on the procedures required to obtain business visas.

Trade Mission members participate in trade missions and undertake mission-related travel at their own risk. The nature of the security situation in a given foreign market at a given time cannot be guaranteed. The U.S. Government does not make any representations or guarantees as to the safety or security of participants. The U.S. Department of State issues U.S. Government international travel alerts and warnings for U.S. citizens available at <https://travel.state.gov/content/passports/en/alertswarnings.html>. Any question regarding insurance coverage

must be resolved by the participant and its insurer of choice.

Definition of Small and Medium Sized Enterprise

For purposes of assessing participation fees, an applicant is a small or medium-sized enterprise (SME) if it qualifies under the Small Business Administration's (SBA) size standards (<https://www.sba.gov/document/support-table-size-standards>), which vary by North American Industry Classification System (NAICS) Code. The SBA Size Standards Tool [<https://www.sba.gov/size-standards/>] can help you determine the qualifications that apply to your company.

Mission List: (additional information about each mission can be found at <http://export.gov/trademissions>).

U.S. Additive Manufacturing Trade Mission to France, Germany, and Poland

Dates: November 18–22, 2019

Summary

The United States (U.S.) Department of Commerce, International Trade Administration's Foreign Commercial Service (USFCS), along with assistance from ITA's Industry & Analysis unit, are organizing an Additive Manufacturing (AM) Trade Mission to France, Germany, and Poland, November 18–22. This mission is designed to help export-ready U.S. companies launch or increase their export business in the rapidly advancing AM and 3D printing industries of France, Germany, and Poland.

Mission participants will benefit from expert briefings, provided by public and private sector specialists, on each country's commercial framework and the local AM market. Strategic focus on AM development, Research & Development (R&D), and commercial integration will be included in the briefings to emphasize American standards and increase competitiveness. The agenda in France and Poland includes meetings with local AM stakeholders, professional associations, one-on-one meetings with potential business partners, and onsite visits with industry leaders. In Germany, delegates will attend the Formnext trade show where they will have the opportunity to participate in discussions on AM standardization, promote their products via a "Pitch Fest", and network with international buyers and stakeholders also attending or exhibiting the show.

The mission will include occur over five business days and involve stops in four cities; Paris, France, Frankfurt, Germany, and Warsaw and Rzeszow,

Poland. Participants will attend site visits at companies active within the AM supply chain, appointments with potential partners, arranged by USFCS, and meetings with national and regional government officials, chambers of

commerce, and business groups. In Germany, attendance at FormNext is included in the mission. There will also be networking opportunities with trade associations representing companies interested in expansion into other

markets and meetings with government authorities to address questions about policies, tariff rates, incentives, regulations, projects, etc.

PROPOSED TIMETABLE

Hour	Activity	Address	Description
Monday, November 18, 2019—Official Start of Mission			
8:30–10:00	Breakfast-Seminar	(TBC)	Presentation of the 3D printing Market in France by President of Multistation (https://www.multistation.com/en/demo-center-paris/) and representative of SYMOP (Trade Association of Machines and Technologies for Production) (TBC).
11:30 a.m.–13:00	Additive Factory Hub in Saclay and/or 4.0 BCG plant in Saclay or Other site (TBD) or B2B meetings if appropriate.	Saclay (91)	TBD.
13:00–14:00	Lunch	TBD.	
15:00–16:30	Visit of Dassault Systèmes 3D Experience Lab in Velizy or B2B meetings if appropriate.	Velizy (78)	TBD.
Frankfurt, Germany—Tuesday, November 19, 2019			
13:00–18:00	FormNext Show		Show visit; one-on-one meetings at the CS booth or at client locations throughout the halls.
19:00	No host dinner	Wegener Restaurant	Participants and invited guests.
Wednesday, November 20, 2019			
9:00–18:00	Formnext Show.		Use of Standards and New Developments in AM Standards.
9:30–12:00	Participation in Standards Events (tentative).		Opportunity for TM members to present their technology.
12:00–12:30	USA Pitch Fest Part I: Quick pitch round for TM members.		Opportunity for TM members to present their technology.
15:00–15:30	USA Pitch Fest Part II		Opportunity for TM members to present their technology.
16:00–16:45	Recent Developments in U.S. Additive Manufacturing.		
17:30–18:30	International Reception		Networking.
Warsaw, Poland—Thursday, November 21, 2019			
9:00	Welcome by Commercial Officer in Warsaw.		
10:00–12:00	Visit of the Institute of Aviation TBC.	Institute of Aviation Aleja Krakowska 110/114, 02–256 Warszawa, Poland.	
12:00–13:00	No host lunch.		
13:00–14:00	Association of Automotive Parts Producers and Distributors.	USFCS offices	Presentation of Automotive sector in Poland TBC.
Rzeszow, Poland—Thursday November 21, 2019			
19:00–21:00	No host informal dinner	Hotel restaurant in Rzeszow: Mikołaja Kopernika 12, 35–069 Rzeszów, Polska.	
Friday, November 22, 2019			
8:30–9:30	Meeting with Aviation Valley	Rzeszów, hotel Bristol	Presentation of aerospace sector in Poland + presentation of all the U.S. companies.
9:30–11:00	Site visit company from automotive sector OR B2B meetings.	TBD.	

PROPOSED TIMETABLE—Continued

Hour	Activity	Address	Description
11:30–12:30	Site visit aerospace company OR B2B meetings.	TBD.	
13:00–14:00	Visit of 3D printing Laboratory.	TBD.	
14:00–15:30	Lunch in hotel Bristol	Hotel Bristol.	
15:30–17:00	B2B meetings	Hotel Bristol.	
17:00	Closing remarks and end of mission.	Hotel Bristol.	

Participation Requirements

All parties interested in participating in the trade mission must submit a complete application for consideration by the U.S. Department of Commerce. All applicants will be evaluated on their market potential and objectives as they relate to the mission stops. The mission will be open on a rolling basis to a minimum of eight and a maximum of 15 firms. Companies must meet the 51% US content rule and eligibility guidelines.

Fees and Expenses

Upon review of an application and acceptance to participate, a payment to the U.S. Department of Commerce in the form of a participation fee is required. The participation fee for the Business Development Mission will be \$3,995 for small or medium-sized enterprises (SME); and \$7,750 for large firms or trade associations. The fee for each additional firm representative (large firm or SME/trade organization) is \$700. Expenses for travel, lodging, meals, and incidentals will be the responsibility of each mission participant. Post in Germany has coordinated with the FormNext show organizer to allow participants entry to its show. Interpreter and driver services can be arranged for an additional cost. Delegation members will be able to take advantage of U.S. Embassy rates for hotel rooms. More detailed travel information and recommended providers will be provided once a company has confirmed participation.

Timeframe for Recruitment and Application

Mission recruitment will be conducted in an open and public manner, including publication in the **Federal Register**, posting on the Commerce Department trade mission calendar (<http://export.gov/trademissions>) and other internet websites, press releases to general and trade media, direct mail, notices by industry trade associations and other multiplier groups, and publicity at industry meetings, symposia,

conferences, and trade shows. Recruitment for the mission will begin immediately and conclude no later than August 30, 2019. The U.S. Department of Commerce will review applications and inform applicants of selection decisions. Applications received after August 30, 2019, will be considered only if space and scheduling constraints permit.

Contacts

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Envirotech Executive Service Mission—Water Delegation to India

Dates: February 9–15, 2020

Summary

The United States Department of Commerce, International Trade Administration, U.S. Commercial Service is organizing the “Envirotech Executive Service” (EES) Mission—Water Delegation to India from February 9–15, 2020, with optional spin-off Gold Key Service in Mumbai or Hyderabad on February 17, 2020.

The “Envirotech Executive Service” (EES) Water Delegation to India is intended to include representatives from up to six U.S. water/wastewater industry manufacturers, service providers, associations, or trade organizations. The EES will introduce the participants to government service providers, end-users and prospective partners whose needs and capabilities are best suited to each U.S. participant’s strengths. Participating in an official U.S. industry delegation, rather than traveling to India on their own, will enhance the participants’ ability to secure business and government meetings in India. The business meetings will be designed to match the delegates with potential business partners, distributors or importers in India. The delegates will meet with government officials to obtain first-hand information about the regulations, policies and procedures for importing into and doing business in India. Participants will also visit facilities to get acquainted with the environmental water/wastewater sector in India. The mission will include appointments and briefings in Delhi, Ahmedabad and Chennai, as well as the opportunity to visit/participate in a local trade show Water Expo 2020 in Chennai. After completion of the EES, delegates can opt for a day of additional Gold Key Service matchmaking meetings in Mumbai or Hyderabad. Each city is one of India’s major water industry hubs. Trade mission participants will have the opportunity to interact extensively with Embassy/Consulate Officials and

Commercial Service India environmental technology specialists to discuss industry developments, opportunities, and sales strategies.

Proposed Timetable

Mission Schedule—February 9–17, 2020

Mission participants are encouraged to arrive on Sunday, February 9, 2020 before the mission program begins on Monday, February 10, 2020.

Sunday—February 9, 2020

- Arrive in Delhi (evening arrival)
- Check into hotel

New Delhi—February 10–11, 2020

Monday—February 10, 2020

- Breakfast/industry briefing on the India water/wastewater market by industry experts
- Full day one-on-one business matchmaking meetings

Tuesday, February 11, 2020

- Customized site visits
- Late afternoon departure for Ahmedabad

Ahmedabad—February 12, 2020

Wednesday, February 12, 2020

- Customized site visit
- One-on-one matchmaking meetings

Chennai—February 13–15, 2020

Thursday, February 13, 2020

- Morning departure for Chennai
- Participation in the inauguration of the Water Expo 2020 trade show and matchmaking meetings

Friday, February 14, 2020

- Full day one-on-one matchmaking meetings at the Water Expo 2020 (with an option to participate in the concurrent trade show conference program)
- Customized site visit

Saturday—February 15, 2020

- Optional visit to the trade show on your own in the morning
- End of program and delegates depart for U.S. or for the optional spin-off stops in Mumbai or Hyderabad

Optional Spin-off Gold Key Service in Mumbai or Hyderabad—February 17, 2020

Monday—February 17, 2020

- Full day one-on-one matchmaking meetings in Mumbai or Hyderabad

Participation Requirements

All parties interested in participating in the EES to India must complete and submit an application for consideration

by the Department of Commerce. All applicants will be evaluated on their ability to meet certain conditions and best satisfy the selection criteria as outlined below. A minimum of 4 and a maximum of 6 companies will be selected to participate in the EES from the applicant pool. U.S. companies already doing business in India as well as U.S. companies seeking to enter the Indian market for the first time may apply.

Fees and Expenses

After a company or organization has been selected to participate on the mission, a payment to the Department of Commerce in the form of a participation fee is required.

The participation fee for the three-city (New Delhi, Ahmedabad and Chennai) Trade Mission will be \$3,460.00 for one principal representative from a small or medium-sized enterprise (SME), or trade organization and \$5,090.00 for large firms. The fee for each additional representative (large firm or SME/trade organization) is \$750.00. The participant fee includes entry to the local trade show Water Expo 2020 in Chennai. Expenses for lodging, some meals, incidentals, and all travel (except for transportation to and from airports in-country, previously noted) will be the responsibility of each mission participant. Additional Gold Key Service matchmaking meetings in Mumbai or Hyderabad will cost \$950 for a small company, \$2,300 for a medium sized company and \$3,400 for a large company.

Timeframe for Recruitment and Application

Mission recruitment will be conducted in an open and public manner, including publication in the **Federal Register**, posting on the Commerce Department trade mission calendar (<http://export.gov/trademissions>) and other internet websites, press releases to general and trade media, direct mail, notices by industry trade associations and other multiplier groups, and publicity at industry meetings, symposia, conferences, and trade shows.

Recruitment for the mission will begin immediately and conclude no later than December 6, 2019. The U.S. Department of Commerce will review applications and make selection decisions on a rolling basis. We will inform all applicants of selection decisions as soon as possible after the applications are reviewed. Applications received after the December 6, 2019 deadline will be considered only if

space and scheduling constraints permit.

Contacts

U.S. Export Assistance Center: Jolanta C. Coffey, Senior International Trade Specialist, U.S. Export Assistance Center, Maryland | U.S. and Foreign Commercial Service, T: 410-962-4578, Jolanta.Coffey@trade.gov.
U.S. Commercial Service in India: Ms. Malarvizhi Parimel, U.S. Commercial Service, American Consulate General, Chennai 600 006, T: (91-44) 2857-4192, 2857-4477, Malarvizhi.Parimel@trade.gov.

Asia EDGE (Enhancing Development and Growth through Energy) Business Development Mission to Indonesia and Vietnam

Date: March 12–20, 2020

Summary

The United States Department of Commerce, International Trade Administration (ITA), is organizing an executive-led Business Development Mission to Southeast Asia, with stops in Indonesia (Jakarta) and Vietnam (Ho Chi Minh City and Hanoi) and an optional program in Thailand (Bangkok).

This trade mission will be the first organized under the Asia Enhancing Development and Economic Growth through Energy (Asia EDGE) initiative. Launched in July 2018 to support the Trump Administration's vision for the Indo-Pacific region, Asia EDGE is a U.S. whole-of-government effort to grow sustainable and secure energy markets throughout Asia by promoting U.S. exports, mobilizing private sector investment, removing trade barriers, and strengthening standards and procurement practices. Drawing on expertise and resources from across the U.S. government, this trade mission will advance the Asia EDGE strategic objective of improving free, fair, and reciprocal energy trading relationships. In addition, the mission will build on several existing energy programs and events, including those organized under the U.S.-Indonesia Power Working Group and the U.S.-Vietnam Energy Working Group.

Mission participants will have the opportunity to meet with key Southeast Asian decision makers to discuss how to foster policies, regulations, and financial investment that support the development of sustainable, secure, and profitable energy markets. Mission participants will network with regional government officials, be introduced to prospective business partners, and facilitate discussions on best practices in their areas of technical expertise.

Participants will gain market insights, make industry contacts, solidify business strategies, discuss enabling policies, and advance specific projects, with the primary goal of increasing U.S. exports of products and services to the Indo-Pacific. The mission will include customized one-on-one business appointments, meetings with government officials, and networking events. Participation will be open to all energy sector stakeholders meeting the prerequisites for participation outlined in the Conditions of Participation below.

Schedule

Proposed Timetable*

*Note: The final schedule of meetings, events, and site visits will depend on the availability of host government and business officials, specific goals of mission participants, and flight availability and ground transportation options.

Sunday, March 15, 2020

- Travel to JAKARTA

Monday, March 16, 2020

- JAKARTA (Full Day Sessions)

Tuesday, March 17, 2020

- JAKARTA (Morning Sessions)
- Travel to HO CHI MINH CITY
- HO CHI MINH CITY (Evening Industry Reception)

Wednesday, March 18, 2020

- HO CHI MINH CITY (Full Day Sessions)

Thursday, March 19, 2020

- Travel to HANOI
- HANOI (Afternoon and Evening Sessions)

Friday, March 20, 2020

- HANOI (Full Day Sessions)
- Official Trade Mission Program Concludes

Saturday/Sunday, March 21–22, 2020

- Optional Spin Off—Travel to BANGKOK

Monday, March 23, 2020

- BANGKOK (Full Day Sessions)

Tuesday, March 24, 2020

- BANGKOK (Morning Sessions)
- Optional Spin Off Program Concludes

Participation Requirements

Applicants must sign and submit a completed trade mission application form and satisfy all the conditions of participation to be eligible for consideration. ITA plans to select a minimum of 10 and a maximum of 15 firms and/or trade associations to participate in the mission.

Fees and Expenses

After a firm or trade association has been selected to participate on the

mission, a payment to the U.S. Department of Commerce in the form of a participation fee is required. The participation fee for this Business Development Mission will be \$4,000 for small or medium-sized enterprises (SME); and \$6,200 for large firms or trade associations. The fee for each additional firm representative (large firm, SME or trade association) is \$1,000. The fee for the spin-off to Bangkok will be \$1,500 for SME; and \$2,400 for large firms or trade associations.

Timeline for Recruitment

Mission recruitment will be conducted in an open and public manner, including publication in the **Federal Register**, posting on the U.S. Department of Commerce trade mission calendar (<http://export.gov/trademissions>) and other internet websites, press releases to general and trade media, direct mail, notices by industry trade associations and other multiplier groups, and publicity at industry meetings, symposia, conferences, and trade shows. Recruitment for the mission will begin immediately.

The Department of Commerce will evaluate applications and inform applicants of selection decisions twice during the recruitment period. All applications received after the first evaluation deadline will be considered during the second evaluation. Deadlines for each round of evaluation are as follows:

- First Round: October 31, 2019
- Final Round: December 2, 2019

Applications received after December 2, 2019, will be considered only if space and scheduling constraints permit.

Contacts

Stephen Anderson, Commercial Officer, U.S. Embassy Bangkok, U.S. Department of Commerce, Phone: 66–2–205–5263, Email:

stephen.anderson@trade.gov

Cathy Gibbons, Global Energy Team

Lead, U.S. Commercial Service, Westchester (New York), U.S. Department of Commerce, Phone: 1–914–682–6712, Email: cathy.gibbons@trade.gov

Victoria Gunderson, International Trade Specialist, Office of Energy and Environmental Industries, U.S. Department of Commerce, Phone: 1–202–482–7890, Email:

victoria.gunderson@trade.gov

Eric Hsu, Senior Commercial Officer, U.S. Embassy Hanoi (Vietnam), U.S. Department of Commerce, Phone: 84–24–3850–5070, Email: eric.hsu@trade.gov

David Nufrio, International Trade Specialist, Global Markets Asia, U.S. Department of Commerce, Phone: 1–202–482–5175, Email: david.nufrio@trade.gov

Paul Taylor, Commercial Officer, U.S. Embassy Jakarta (Indonesia), U.S. Department of Commerce, Phone: 62–815–1080–0475, Email: paul.taylor@trade.gov

Trade Mission to Hong Kong and Indo-Pacific in Conjunction With Trade Winds Indo-Pacific

Date: April 20–28, 2020

Summary

The United States Department of Commerce, International Trade Administration, U.S. and Foreign Commercial Service (USFCS) is organizing a trade mission to Hong Kong and the Indo Pacific region, that will include the Trade Winds Indo Pacific business forum in Hong Kong, April 20–28, 2020. U.S. trade mission members will participate in the Trade Winds—Indo Pacific business forum in Hong Kong (which is also open to U.S. companies not participating in the trade mission). Trade mission participants may participate in their choice of mission stops based on recommendations from the USFCS. Each trade mission stop will include one-on-one business appointments with pre-screened potential buyers, agents, distributors and joint-venture partners, and networking events. Trade mission participants electing to participate in the Trade Winds Indo Pacific business forum may attend regional consultations with USFCS Senior Commercial Officers and Officers from participating State Department Partner Posts.

This mission is open to U.S. companies from a cross section of industries with growth potential in Hong Kong and the Indo Pacific region, including but not limited to: Aerospace and defense, consumer goods, energy, franchising, healthcare, environmental technologies, information & communication technologies, design & construction, and environmental technologies.

Proposed Timetable

This timetable allows for clients to take part in business matchmaking across the diverse Indo Pacific marketplace by offering scheduled business-to-business meetings in Hong Kong, South Korea, Japan, Thailand, and Vietnam. This structure ensures that each post has set days for meetings that allow the clients to explore up to three of their best prospects for business.

Sunday April 19, 2020

Trade Mission Participants Arrive in Japan or Vietnam (if electing to participate in one of these mission stops)

Monday April 20, 2020

Japan or Vietnam (choice of one mission stop) Business to Business meetings and networking with government and business officials

Tuesday April 21, 2020

Arrive in Hong Kong

Wednesday–Friday, April 22–24, 2020

Hong Kong: Trade Winds Business Forum and SCO Consultations Market Briefings, Business to Business meetings, Consultations with U.S. government trade representatives and networking with U.S. and foreign government and business officials

Saturday–Sunday, April 25–26, 2020

Travel to South Korea or Thailand (if electing to participate in one of these mission stops)

Monday April 27, 2020

South Korea or Thailand (choice of one mission stop) Business to Business meetings and networking with government and business officials

Tuesday April 28, 2020

Trade Mission Participants Depart

Participation Requirements

All parties interested in participating in the trade mission to Hong Kong (including mission stops with business matchmaking in Hong Kong and/or additional countries) must complete and submit an application package for consideration by the Department of Commerce. All applicants will be evaluated on their ability to meet certain conditions and best satisfy the selection criteria as outlined below.

A minimum of 40 companies and/or trade associations will be selected to participate in the mission from the applicant pool on a rolling basis. Mission stop participation will be limited as follows:

Business matchmaking capacity:

Hong Kong—32
South Korea—20
Japan—20
Thailand—20
Vietnam—20

Additional companies may be accepted based on available space. U.S. companies and/or trade associations already doing business in or seeking business in Hong Kong, South Korea, Japan, Thailand, or Vietnam for the first time may apply.

Fees and Expenses

If and when an applicant is selected to participate on a particular mission, a

payment to the Department of Commerce in the amount of the designated participation fee below is required. Upon notification of acceptance to participate, those selected have 5 business days to submit payment or the acceptance may be revoked.

The below trade mission fees include the \$750 participation fee for the Trade Winds business forum to be held in Hong Kong on April 20–28, 2020.

1. For one mission stop, the participation fee will be \$2,200 for a small or medium-sized enterprise (SME) and \$4,200 for large firms.

2. For two mission stops, the participation fee will be \$3,400 for a small or medium-sized enterprise (SME) and \$5,400 for large firms.

3. For three mission stops, the participation fee will be \$4,600 for a small or medium-sized enterprise (SME) and \$6,600 for large firms.

4. For four mission stops, the participation fee will be \$5,800 for a small or medium-sized enterprise (SME) and \$7,800 for large firms.

An additional representative for both SMEs and large firms at the Forum will require an additional fee of \$500.

Timeframe for Recruitment and Application

Mission recruitment will be conducted in an open and public manner, including publication in the **Federal Register**, posting on the Commerce Department trade mission calendar (<http://export.gov/trademissions>) and other internet websites, press releases to general and trade media, direct mail, notices by industry trade associations and other multiplier groups, and publicity at industry meetings, symposia, conferences, and trade shows.

Recruitment for the mission will begin immediately and conclude no later than March 6, 2020. The U.S. Department of Commerce will review applications and make selection decisions on a rolling basis beginning 14 DAYS AFTER PUBLICATION OF THE **FEDERAL REGISTER NOTICE**, until the maximum number of participants is selected. After March 6, 2020, applications will be considered only if space and scheduling constraints permit.

Contacts

Colleen Fisher, Director, U.S. Export Assistance Center—Baltimore, MD, Colleen.Fisher@trade.gov, Tel: 410–962–3097

Leandro Solorzano, Trade Specialist, U.S. Export Assistance Center—Fort Lauderdale, FL, Leandro.Solorzano@trade.gov, Tel: 954–356–6647

International Contact Information, Geoffrey Parish, Deputy Senior Commercial Officer, U.S. Commercial Service Hong Kong, Email: Geoffrey.Parish@trade.gov

Tiara Hampton-Diggs,

Program Specialist, Trade Promotion Programs.

[FR Doc. 2019–19966 Filed 9–13–19; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

RIN 0648–XV067

Mid-Atlantic Fishery Management Council (MAFMC); Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold public meetings of the Council and its Committees.

DATES: The meetings will be held Monday, October 7, 2019, from 9 a.m. to 5 p.m.; Tuesday, October 8, 2019, from 9 a.m. to 5 p.m.; Wednesday, October 9, 2019, from 9 a.m. to 5 p.m.; and, Thursday, October 10, 2019, from 9 a.m. to 1 p.m. For agenda details, see

SUPPLEMENTARY INFORMATION.

ADDRESSES: The meeting will be held at the Durham Convention Center, 301 W. Morgan St., Durham, NC 27701; telephone: (919) 956–9404.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State St., Suite 201, Dover, DE 19901; telephone: (302) 674–2331.

FOR FURTHER INFORMATION CONTACT:

Christopher M. Moore, Ph.D. Executive Director, Mid-Atlantic Fishery Management Council; telephone: (302) 526–5255. The Council's website, www.mafmc.org also has details on the meeting location, proposed agenda, webinar listen-in access, and briefing materials.

SUPPLEMENTARY INFORMATION: The following items are on the agenda, though agenda items may be addressed out of order (changes will be noted on the Council's website when possible.)

Monday, October 7, 2019

Executive Committee (Closed Session)

Review and approve changes to SOPPs

Executive Committee Meeting

Review progress on 2019 Implementation Plan and develop recommendations for 2020 priorities

Monkfish Specifications

Summary of Operational Assessment and review SSC, PDT, Advisory Panel and staff recommendations and adopt specifications for 2020–22

Spiny Dogfish Specifications

Review, SSC, Monitoring Committee, Advisory Panel, and staff recommendations for 2020 specifications and recommend any changes if necessary

Illex Permitting and Atlantic Mackerel, Squid, Butterfish Goals and Objectives Amendment

Review Committee recommendations and provide direction to staff on Amendment development

Illex In-Year Quota Adjustment Working Group

Review Working Group Terms of Reference

2020–24 Comprehensive Research Priorities

Review and provide feedback on draft research priorities

Tuesday, October 8, 2019*Summary of Operational Assessments for Scup, Black Sea Bass, and Bluefish Bluefish Specifications*

Review SSC, Monitoring Committee, Advisory Panel, and staff recommendations and adopt revised specifications for 2020 and new specifications for 2021

Bluefish Allocation Amendment

Discuss current status of the Bluefish Allocation Amendment and review the updated action plan

Scup Commercial Discards Report

Review commercial scup discards through 2018

Scup Specifications

Review SSC, Monitoring Committee, Advisory Panel, and staff recommendations and adopt revised specifications for 2020 and new specifications for 2021

Summer Flounder Specifications

Review SSC, Monitoring Committee, Advisory Panel, and staff recommendations for 2020 specifications and review previously implemented 2020 specifications and recommend changes if necessary

Wednesday, October 9, 2019*Black Sea Bass Specifications*

Review SSC, Monitoring Committee, Advisory Panel, and staff recommendations and adopt revised specifications for 2020 and new specifications for 2021

Summer Flounder, Scup, and Black Sea Bass Commercial/Recreational Allocations

Discuss implications of revised MRIP data for sector allocations defined in FMP's and consider initiating an amendment to address commercial and recreational allocations for all three species

Potential Black Sea Bass Commercial Amendment

Update on ASMFC discussions regarding state-by-state commercial quota allocations and consider initiating an amendment to address black sea bass commercial state-by-state allocations

Recreational Reform Initiative

Progress update on recreational management reform initiative focused on black sea bass, summer flounder, scup, and bluefish

2020–24 Strategic Plan

Review draft 2020–24 Strategic Plan

Thursday, October 10, 2019*Business Session*

Committee Reports: SSC and Executive (review and approve SOPP recommendations); Executive Director's Report; Organization Reports; and, Liaison Reports

Continuing and New Business

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during these meetings. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid

should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

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

Dated: September 11, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019–19958 Filed 9–13–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

RIN 0648–XV071

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The North Pacific Fishery Management Council (Council) Legislative Committee will meet in October.

DATES: The meeting will be held on Wednesday, October 2, 2019, from 3 p.m. to 5 p.m.

ADDRESSES: The meeting will be held at the Land's End Resort, 4786 Homer Spit Rd, Homer, AK 99603.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252; telephone: (907) 271–2809.

FOR FURTHER INFORMATION CONTACT: David Witherell, Council staff; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION:**Agenda**

The agenda will include updates on legislation, including HR 1979 and HR 2236, and development of recommendations for the Council.

The Agenda is subject to change, and the latest version will be posted at meetings.npfmc.org/Meeting/Details/923.

Public Comment

Public comment letters will be accepted and should be submitted either electronically at: meetings.npfmc.org/Meeting/Details/923 or through the mail: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252. Deadline for comments is September 27, 2019, at 12 p.m.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shannon Gleason at (907) 271-2809 at least 7 working days prior to the meeting date.

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

Dated: September 11, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019-19962 Filed 9-13-19; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XV072

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council will hold a meeting of its Law Enforcement Technical Committee (LETC), in conjunction with the Gulf States Marine Fisheries Commission's Law Enforcement Committee (LEC).

DATES: The meeting will convene on Wednesday, October 16, 2019; starting 8:30 a.m. and will adjourn at 5 p.m.

ADDRESSES: The meeting will be held at the Golden Nugget Biloxi Hotel and Casino, 151 Beach Blvd., Biloxi, MS 39530; telephone (228) 535-5400.

Council address: Gulf of Mexico Fishery Management Council, 4107 W Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348-1630.

FOR FURTHER INFORMATION CONTACT: Dr. Ava Lasseter, Anthropologist, Gulf of Mexico Fishery Management Council; ava.lasseter@gulfcouncil.org, telephone: (813) 348-1630, and Mr. Steve Vanderkooy, Inter-jurisdictional Fisheries (IJF) Coordinator, Gulf States Marine Fisheries Commission; svanderkooy@gsmfc.org, telephone: (228) 875-5912.

SUPPLEMENTARY INFORMATION: The items of discussion on the agenda are as follows:

Joint Gulf Council's Law Enforcement Technical Committee and Gulf States Marine Fisheries Commission's Law Enforcement Committee Meeting Agenda, Wednesday, October 16, 2019, 8:30 a.m. Until 5 p.m.

1. Introductions and Adoption of Agenda
2. Approval of Minutes (Joint Meeting March 20, 2019)

Gulf Council LETC Items

3. IUU Fishing—Coordinating Responses to Federal Determination Regarding Mexico's Certification
4. Possession Limits on For-Hire Trips Over 24 Hours
5. Recreational Greater Amberjack—Fractional Bag Limits
6. Commercial IFQ Program Modifications—Estimated Weights in Advance Landing Notifications
7. SEFHEIR—Onboard Electronic Monitoring and Reporting (EM/ER) Systems in the Gulf Region For-Hire (Charter and Guide) Vessels
8. Maximum Crew Size on Dual-Permitted (Commercial and For-Hire) Vessels Fishing in Federal Waters
9. EFPs/State Management—Enforcement of Red Snapper Seasons
10. Officer/Team of the Year Award Update
11. LETC Other Business

GSMFC LEC Items

12. Future of Joint Enforcement Agencies (JEAs) and JEA Funding Discussion
13. Status of State Waters FADs
14. IJF Program Activity
 - a. Red Drum Profile Status
 - b. Mangrove Snapper Profile LE Membership
 - c. Annual License and Fees
 - d. Law Summary (red book)
15. State Report Highlights
 - a. Florida
 - b. Alabama
 - c. Mississippi
 - d. Louisiana
 - e. Texas
 - f. USCG
 - g. NOAA OLE
 - h. USFWS
16. Other Business

—Meeting Adjourns

The Agenda is subject to change, and the latest version along with other meeting materials will be posted on www.gulfcouncil.org as they become available.

The Law Enforcement Technical Committee consists of principal law enforcement officers in each of the Gulf States, as well as the NOAA Law

Enforcement, U.S. Fish and Wildlife Service, the U.S. Coast Guard, and the NOAA General Counsel for Law Enforcement.

Although other non-emergency issues not on the agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during this meeting. Actions will be restricted to those issues specifically identified in the agenda and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Gulf Council Office (see **ADDRESSES**), at least 5 working days prior to the meeting.

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

Dated: September 11, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019-19963 Filed 9-13-19; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XV073

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council will hold a two-day meeting, Release Mortality Science Workshop.

DATES: The meeting will convene at 8:30 a.m. on Monday, October 7 and conclude at 12 p.m., EDT on Tuesday, October 8, 2019. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held at the Tradewinds Island Resort, located at 5600 Gulf Boulevard, St. Petersburg Beach, FL; telephone: (727) 363-2215.

Council address: Gulf of Mexico Fishery Management Council, 4107 W. Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348-1630.

FOR FURTHER INFORMATION CONTACT: Emily Muehlstein, Public Information Officer, Gulf of Mexico Fishery Management Council; emily.muehlstein@gulfcouncil.org, telephone: (813) 348-1630. The Council's website, www.gulfcouncil.org also has details on the meeting location, proposed agenda, webinar listen-in access, and other materials.

SUPPLEMENTARY INFORMATION: The following items are on the agenda, though agenda items may be addressed out of order (changes will be noted on the Council's website when possible.)

Monday, October 7, 2019; 8:30 a.m.–5 p.m.

The meeting will begin with Welcome and Introductions of members; followed by a number of presentations on Magnitude of Discard Mortality of Reef Fish in the Gulf of Mexico; Eastern Gulf: A Synopsis of Research on Recreational Fishing Practices and Discard Mortality; Northern Gulf: A Synopsis of Research on Discard Mortality; Western Gulf: A Synopsis of Research on Recreational Fishing Practices and Discard Mortality; and, a presentation on West Coast Success story: Yelloweye Rockfish Barotrauma Mitigation and Incorporation into Management and Stock Assessment Process.

After lunch, we will hold a facilitated discussion on Barotrauma Mitigation by Fleet and Reef Fish Species; build a barotrauma risk matrix, discuss best practices and devices for each fleet, and the rationale and barriers for methods.

Tuesday, October 8, 2019; 8:30 a.m.–12 p.m.

We will receive a presentation on Overview of stock assessment inputs affected by release and release mortality rates; followed by a facilitated discussion to define necessary stock assessment inputs; suggest barotrauma mitigation research that could benefit stock assessments using existing monitoring frameworks and through novel research efforts; and, prioritize data gaps by species, fleets, and region.—Meeting Adjourns

The meeting will be broadcast via webinar. You may register for the listen-in access by visiting www.gulfcouncil.org and clicking on the meeting on the calendar. The Agenda is subject to change, and the latest version along with other meeting materials will be posted on www.gulfcouncil.org as they become available.

Although other non-emergency issues not on the agenda may come before the group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during this meeting. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Gulf Council Office (see **ADDRESSES**), at least 5 working days prior to the meeting.

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

Dated: September 11, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019-19964 Filed 9-13-19; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XH002

Schedules for Atlantic Shark Identification Workshops and Safe Handling, Release, and Identification Workshops; Correction

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

ACTION: Notice of public workshops; correction.

SUMMARY: NMFS announces that the date for the Safe Handling, Release, and Identification workshop originally scheduled for September 4, 2019, in Warwick, RI, has been changed to September 23, 2019. The date is being changed because inclement weather resulting from Hurricane Dorian prevented the instructors from traveling safely to the original workshop. The workshop time and location remains unchanged: 9 a.m. to 5 p.m. in Warwick, RI. The remaining September 2019, workshop in Panama City, FL, also remains unchanged. Safe Handling, Release, and Identification workshop

are mandatory for shark and swordfish limited-access permit holders who fish with longline or gillnet gear. Additional free workshops will be conducted during 2019.

DATES: The date for the Safe Handling, Release, and Identification workshop to be held in Warwick, RI, is changed to September 23, 2019. See **SUPPLEMENTARY INFORMATION** for further details.

ADDRESSES: The address for the Safe Handling, Release, and Identification workshop to be held in Warwick, RI, remains at the Hilton Garden Inn, 1 Thurber Street, Warwick, RI 02886. See **SUPPLEMENTARY INFORMATION** for further details.

FOR FURTHER INFORMATION CONTACT: Rick Pearson by phone: (727) 824-5399.

SUPPLEMENTARY INFORMATION: The workshop schedules, registration information, and a list of frequently asked questions regarding these workshops are posted on the internet at: <https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/safe-handling-release-and-identification-workshops>.

Correction

In the **Federal Register** (Doc. 2019-12407) of June 12, 2019, on page 27288, in the first column, correct the date of the fifth Safe Handling, Release, and Identification workshop listed under the heading *Workshop Dates, Times, and Locations* to read:

“5. September 23, 2019, 9 a.m.–5 p.m., Hilton Garden Inn, 1 Thurber Street, Warwick, RI 02886.”

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

Dated: September 11, 2019.

Jennifer M. Wallace,

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

[FR Doc. 2019-19931 Filed 9-13-19; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XV070

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council will hold a one-day meeting of its Outreach & Education Technical Committee.

DATES: The meeting will convene on Wednesday, October 9, 2019, from 8:30 a.m. to 5 p.m., EDT. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held at the Tradewinds Island Resort, located at 5600 Gulf Boulevard, St. Petersburg Beach, FL; telephone: (727) 363-2215.

Council address: Gulf of Mexico Fishery Management Council, 4107 W. Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348-1630.

FOR FURTHER INFORMATION CONTACT: Emily Muehlstein, Public Information Officer, Gulf of Mexico Fishery Management Council; emily.muehlstein@gulfcouncil.org, telephone: (813) 348-1630. The Council's website, www.gulfcouncil.org also has details on the meeting location, proposed agenda, webinar listen-in access, and other materials.

SUPPLEMENTARY INFORMATION: The following items are on the agenda, though agenda items may be addressed out of order (changes will be noted on the Council's website when possible.)

Wednesday, October 9, 2019; 8:30 a.m.–5 p.m.

Introductions of members, election of new chair, adoption of agenda, and approval of minutes from the May 2018 meeting summary. The committee will hear presentations on “Recreational Angler Perceptions Regarding the Use of Descending Devices in Southeast Reef Fish Fisheries” and “Barotrauma Mitigation and the Power of Subjective Norms in Florida’s Reef Fish Fisheries.” The committee will review and discuss Gulf-wide Outreach/Communications Strategies to Reduce Barotrauma in Recreational Fisheries; Highlight specific approaches for For-Hire and private fleets and identify specific influencers across the region (media, business, and community leaders). The Committee will review the Council’s

new “Fishing for Our Future” best practices website and hear a presentation on the Gulf Council’s Communications Analytics. The committee will discuss any Other Business items.

— Meeting Adjourns

The meeting will be broadcast via webinar. You may register for the listen-in access by visiting www.gulfcouncil.org and clicking on the meeting on the calendar.

The Agenda is subject to change, and the latest version along with other meeting materials will be posted on www.gulfcouncil.org as they become available.

Although other non-emergency issues not on the agenda may come before the group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during this meeting. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council’s intent to take action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Gulf Council Office (see **ADDRESSES**), at least 5 working days prior to the meeting.

Dated: September 11, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019-19961 Filed 9-13-19; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Marine Mammals and Endangered Species

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

ACTION: Notice; issuance of permits and permit amendments.

SUMMARY: Notice is hereby given that permits or permit amendments have been issued to the following entities under the Marine Mammal Protection Act (MMPA) and the Endangered Species Act (ESA), as applicable.

ADDRESSES: The permits and related documents are available for review upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone: (301) 427-8401; fax: (301) 713-0376.

FOR FURTHER INFORMATION CONTACT: Shasta McClenahan (Permit Nos. 20430-01, 21476, and 22750) and Courtney Smith (Permit No. 21321-01); at (301) 427-8401.

SUPPLEMENTARY INFORMATION: Notices were published in the **Federal Register** on the dates listed below that requests for a permit or permit amendment had been submitted by the below-named applicants. To locate the **Federal Register** notice that announced our receipt of the application and a complete description of the research, go to www.federalregister.gov and search on the permit number provided in the table below.

Permit No.	RIN	Applicant	Previous Federal Register notice	Permit or amendment issuance date
20430-01	0648-XE938	James Harvey, Ph.D., Moss Landing Marine Laboratories, 8272 Moss Landing Road, Moss Landing, CA 95039.	84 FR 30092; June 26, 2019.	August 27, 2019.
21321-01	0648-XG047	Pacific Whale Foundation (Responsible Party: Stephanie Stack), 300 Ma'alaea Rd., Suite 211 Wailuku, HI 96793.	84 FR 26074; June 5, 2019.	August 27, 2019.
21476	0648-XG853	Lars Bejder, Ph.D., University of Hawaii at Manoa, 46-007 Lilipuna Road, Kaneohe, HI 96744.	84 FR 13908; April 8, 2019.	August 27, 2019.
22750	0648-XG854	Rachel Cartwright, Ph.D., Keiki Kohola Project, 1330 Sabal Lakes Road, Delray Beach, FL 33445.	84 FR 15598; April 16, 2019.	August 27, 2019.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the

activities proposed are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

As required by the ESA, as applicable, issuance of these permit was based on a finding that such permits: (1) Were applied for in good faith; (2) will not

operate to the disadvantage of such endangered species; and (3) are consistent with the purposes and policies set forth in Section 2 of the ESA.

Authority: The requested permits have been issued under the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), as applicable.

Dated: September 10, 2019.

Julia Marie Harrison,

*Chief, Permits and Conservation Division,
Office of Protected Resources, National
Marine Fisheries Service.*

[FR Doc. 2019–19935 Filed 9–13–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XV069

New England Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Scientific & Statistical Committee to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Thursday, October 17, 2019, beginning at 10 a.m. and Friday, October 18, 2019, beginning at 9 a.m.

ADDRESSES: The meeting will be held at the Hilton Garden Inn, Boston Logan, 100 Boardman Street, Boston, MA 02128; phone: (617) 567–6789.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Scientific and Statistical Committee will:

Review recent stock assessment information from the 2017 Groundfish Management Track Assessments, information provided by the Council's Groundfish Plan Development Team (PDT) and recommend the overfishing levels and acceptable biological catch for Georges Bank (GB) cod, Gulf of Maine (GOM) cod, GB haddock, GOM haddock, Cape Cod/GOM yellowtail flounder, Southern New England/Mid-Atlantic yellowtail flounder, GB winter flounder, American plaice, witch flounder, pollock, white hake, Atlantic halibut, Northern windowpane flounder, and Southern windowpane flounder for fishing years 2020–21. They will also review the information provided by the Council's Scallop PDT and recommend the overfishing levels (OFLs) and acceptable biological catches (ABCs) for Atlantic sea scallops for fishing years 2020–21 (default). Other business will be discussed as needed.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded, consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: September 11, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019–19960 Filed 9–13–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XV068

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council will hold a one-day meeting of its Reef Fish Advisory Panel (AP).

DATES: The meeting will convene on Wednesday, October 2, 2019, 8:30 a.m. to 5:30 p.m., EDT. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held at the Gulf Council office.

Council address: Gulf of Mexico Fishery Management Council, 4107 W Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Ryan Rindone, Fishery Biologist, Gulf of Mexico Fishery Management Council; ryan.rindone@gulfcouncil.org; telephone: (813) 348–1630. The Council's website, www.gulfcouncil.org also has details on the meeting location, proposed agenda, webinar listen-in access, and other materials.

SUPPLEMENTARY INFORMATION: The following items are on the agenda, though agenda items may be addressed out of order (changes will be noted on the Council's website when possible.)

Wednesday, October 2, 2019; 8:30 a.m.–5:30 p.m.

Introduction of members, adoption of agenda, and approval of minutes from the May 9, 2019 meeting (webinar). Staff will review the Scope of Work; and, hold an election for the Chair and Vice Chair seats. The AP will receive presentations on SEDAR 61: Gulf of Mexico Red Grouper Stock Assessment and an update on SEDAR 49: Gulf of Mexico Lane Snapper Itarget Assessment, along with the SSC Recommendations for Overfishing Limits (OFL) and Acceptable Biological Catch (ABC) for both; and, review the SEDAR 61 Executive Summary. The AP will receive updates on Florida Keys National Marine Sanctuary Expansion: Sanctuary Plan and Comments; Flower Garden Banks National Marine Sanctuary Expansion; and, the progress for Coral Amendment 9.

The AP will review draft Framework Action to Modify Greater Amberjack

Recreational Management Measures; receive a summary of Reef Fish AP Decisions on Greater Amberjack Bag Limits; and discuss a New Action considering Recreational Zone Management. The AP will receive a status update for Draft Amendment 52: Reallocation of Red Snapper; review Draft Amendment 36B: Modifications to Commercial IFQ Programs and Presentation and Draft Framework Action to Modify Multi-day Possession Limits for For-hire Vessels; and, hold a discussion for removing the rule allowing trolling in the Steamboat Lumps MPA and perhaps Madison Swanson.

The Chair will discuss any other business items.

—Meeting Adjourns

The meeting will be broadcast via webinar. You may register for the listen-in access by visiting www.gulfcouncil.org and clicking on the AP meeting on the calendar.

The Agenda is subject to change, and the latest version along with other meeting materials will be posted on www.gulfcouncil.org as they become available.

Although other non-emergency issues not on the agenda may come before the group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during this meeting. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Gulf Council Office (see **ADDRESSES**), at least 5 working days prior to the meeting.

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

Dated: September 11, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019-19959 Filed 9-13-19; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD-2019-OS-0086]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 16, 2019.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at oira_submission@omb.eop.gov. Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT:

Angela James, 571-372-7574, or whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Application for Correction of Military Records Under the Provisions of Title 10, U.S. Code, Section 1552; DD Form 149; OMB Control Number 0704-0003.

Type of Request: Revision.

Number of Respondents: 36,110.

Responses per Respondent: 1.

Annual Responses: 36,110.

Average Burden per Response: 30 minutes.

Annual Burden Hours: 18,055.

Needs and Uses: The information collected from the DD Form 149 is used by the respective Military Department Correction Boards to determine if an error or injustice has occurred in an individual's military record and to promulgate a correction based on justice, equity, and compassion.

Affected Public: Individuals or households.

Frequency: As required.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

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

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

Dated: September 11, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019-19980 Filed 9-13-19; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD-2019-OS-0085]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 16, 2019.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at oira_submission@omb.eop.gov. Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT:

Angela James, 571-372-7574, or whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Application for the Review of Discharge or Dismissal from the Armed Forces of the United States; DD Form 293; OMB Control Number 0704-0004.

Type of Request: Revision.

Number of Respondents: 10,000.

Responses per Respondent: 1.
Annual Responses: 10,000.
Average Burden per Response: 30 minutes.

Annual Burden Hours: 5,000.

Needs and Uses: The information collection is needed to provide Service members a method to present to their respective Military Department Discharge Review Boards their reason/justification for a discharge upgrade as well as providing the Military Departments with the basic data needed to process the appeal.

Affected Public: Individuals or households.

Frequency: As required.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

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

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

Dated: September 11, 2019.

Aaron T. Siegel,

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

[FR Doc. 2019-19997 Filed 9-13-19; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2019-ICCD-0074]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Foreign Schools Eligibility Criteria Apply To Participate in Title IV HEA Programs

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 October 16, 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-0074. 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 www.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 Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9086, Washington, DC 20202-0023.

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: Foreign Schools Eligibility Criteria Apply to Participate in Title IV HEA Programs.

OMB Control Number: 1845-0105.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Individuals or Households; Private Sector; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 26,713.

Total Estimated Number of Annual Burden Hours: 7,230.

Abstract: The information in 34 CFR Sections 600.54, 600.55, 600.56, and 600.57 is used by the Department during the initial review for eligibility certification, recertification and annual evaluations. These regulations help to ensure that all foreign institutions participating in the Title IV, HEA programs are meeting the minimum participation standards.

Dated: September 11, 2019.

Kate Mullan,

PRA Coordinator, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.

[FR Doc. 2019-19950 Filed 9-13-19; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

Notice Announcing Availability of Funds and Application Deadline; Emergency Assistance to Institutions of Higher Education

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice announcing the availability of funds and the application deadline for new grants to institutions of higher education (IHEs) under the Emergency Assistance to Institutions of Higher Education (2019 EAI) Program, Catalog of Federal Domestic Assistance (CFDA) number 84.938T, under title VIII of the Additional Supplemental Appropriations for Disaster Relief Act of 2019 (hereafter referred to as the Disaster Supplemental), for education-related disaster recovery activities

related to disasters in 2018 and 2019 for which a major disaster or emergency has been declared by the President. Refer to the *Purposes of Program* section for more information on specific disasters that are covered by this program funding. This notice relates to the approved information collection under OMB control number 1840–0839.

DATES:

Applications Available: September 16, 2019.

Deadline for Transmittal of Applications: October 28, 2019.

ADDRESSES: The addresses pertinent to this program, including the addresses for obtaining and submitting an application, can be found under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT:

Beatriz Ceja, U.S. Department of Education, 400 Maryland Avenue SW, Room 260–04, Washington, DC 20202. Telephone: (202) 453–6239. Email: EAIProgram@ed.gov.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purposes of Program: Under the 2019 EAI Program, we will award grants for emergency assistance to eligible IHEs affected by Hurricanes Florence and Michael, Typhoon Mangkhut, Super Typhoon Yutu, and wildfires, earthquakes, and volcanic eruptions occurring in calendar year 2018 and tornadoes and floods occurring in calendar year 2019 for which a major disaster or emergency has been declared under section 401 or 501 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5170 and 5191) (hereafter referred to as “a covered disaster or emergency”). Funds will be awarded to assist activities directly related to mitigating the effects of a covered disaster or emergency on students and institutions. To the extent possible, we will prioritize projects that support students who are homeless or who are at risk of becoming homeless as a result of displacement related to a covered disaster or emergency; and IHEs that have sustained extensive damage by a covered disaster or emergency.

Background: The Additional Supplemental Appropriations for Disaster Relief Act, 2019 (hereafter referred to as the Disaster Supplemental), Public Law 116–20,

which was signed into law on June 6, 2019, provided a total of \$165 million for education-related disaster recovery programs and gave the Secretary of Education discretion regarding how best to administer those funds to meet the needs of eligible entities at the elementary, secondary, and postsecondary levels of education. The Department has determined that the EAI Program is the most flexible and efficient authority for addressing the needs of institutions of higher education affected by a covered disaster or emergency. The Department also is using these funds to provide assistance to public and non-public elementary and secondary schools under the Immediate Aid to Restart School Operations (Restart) and the Temporary Emergency Impact Aid for Displaced Students (EIA) programs.

Exemption from Rulemaking: The 2019 EAI Program is exempt from the rulemaking requirements in section 437 of the General Education Provisions Act (GEPA) (20 U.S.C. 1232) and section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553), as established in division B, subdivision 1, title VIII, “Hurricane Education Recovery” paragraph (6), of Public Law 115–123, the Bipartisan Budget Act of 2018, and title VIII of Public Law 116–20, the Disaster Supplemental.

Program Authority: Title VIII of the Disaster Supplemental.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474.

Note: The open licensing requirement in 2 CFR 3474.20 does not apply to this program.

II. Award Information

Estimated Available Funds: Congress appropriated \$165 million to the Department under the Disaster Supplemental that will be used to make awards under this program and others authorized in the law. Consequently, the specific amount available for the 2019 EAI Program will be based on the Department’s assessment of relative need across funded programs as determined by such factors as the

number of applicants and their demonstrated need for assistance. The actual amount available for 2019 EAI awards will depend on funding allocated to the program, and awards to eligible applicants may be adjusted downward (or upward) to match available funding and award allocations as described in this notice.

Estimated Range of Awards: We will not make an award that, in combination with the total amount of reimbursement received by the IHE from insurance claims or other relief funds, would exceed the IHE’s total net need.

Estimated Number of Awards: The Department does not yet have reliable estimates of the number of institutions that may be eligible or apply for 2019 EAI awards but intends to make awards to all eligible applicants.

Note: The Department is not bound by any estimates in this notice.

Grant Period under the 2019 EAI Program: IHEs must expend funds received under this program within 24 months of obligation by the Department. Funds are available for obligation by the Department through September 30, 2020.

III. Eligibility Information

1. *Eligible Applicants:* Institutions that (1) meet the definition of “institution of higher education” in section 101 or section 102(a)(1) of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. 1001 and 1002(a)(1)), (2) are located in areas directly affected by a covered disaster or emergency, and (3) that have education-related financial needs resulting from a covered disaster or emergency. A general list of disaster declarations and emergency declarations can be found at www.fema.gov/disasters.

Note: Receiving a grant for emergency assistance under the 2019 EAI Program does not affect the eligibility of the IHE to apply for funding under any other Department program.

2. (a) *Cost Sharing or Matching:* This program does not require cost sharing or matching.

(b) *Supplement-Not-Supplant:* This program involves supplement-not-supplant funding requirements. Grantees may not use 2019 EAI funds to supplant funds that otherwise would have been used for the same purpose, including funds made available through an insurance policy, the Federal Emergency Management Agency, a State, or a nonprofit relief organization. Grantees may use 2019 EAI funds to supplement funds from such sources without exceeding the full amount needed to remedy the effects of the

covered disaster or emergency. (See Allocation Criteria.)

3. *Subgrantees*: A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

IV. Application and Submission Information

1. Application Submission

Instructions: Applications for this program must be submitted in both of the following ways:

(a) Submit an application in electronic portable document format (PDF) or Microsoft Word format via email to EAIProgram@ed.gov. Questions regarding application submission can be directed to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

(b) Mail the original and two copies of your application by express mail service through the U.S. Postal Service or through a commercial carrier to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

2. *Intergovernmental Review*: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. However, under 34 CFR 79.8(a), we waive intergovernmental review in order to make timely awards.

3. *Funding Restrictions*: We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

4. *Recommended Page Limit*: The application narrative (Part III of the application) is where you, the applicant, address the allocation criteria that Department staff will use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 20 pages and (2) use the following standards:

- A “page” is 8.5” × 11”, on one side only, with 1” margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative. Titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs, are excluded.
- Use a font that is either 12 point or larger, and no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications. The page limit is recommended and non-binding.

V. Application Review Information

1. *Institution’s Data*: IHEs which apply for grants must provide the following data: The number of days the institution was closed as a result of the covered disaster or emergency; the institution’s student enrollment prior to the disaster; the institution’s student enrollment after the disaster; the number of students to whom the institution intends to provide direct assistance using 2019 EAI funding; and the number of students the institution knows to be homeless or at risk of being homeless.

2. *Needs and Severity Narrative*: Applicants must describe the covered disaster’s or emergency’s impact on the institution and the need for funds. Applicants must also describe the severity of the damage to the institution’s ability to return to full capacity.

3. *Proposed Use of Funds*: To the extent possible, applicants must identify the proposed or actual services or assistance to be paid for with the requested grant funds and explain how the services or assistance is consistent with the allowable uses of funds under the 2019 EAI Program.

Note: Allowable uses of funds include those authorized under the HEA. However, all activities funded under the program must be in the context of emergency assistance. That is, the funding must be used for activities directly related to mitigating the effects of a covered disaster or emergency on students and institutions. For instance, program funds may be used for student financial assistance, faculty and staff salaries, equipment, and student supplies and instruments. Grantees may not use program funds to supplant funds that otherwise would have been used for the same purpose, such as funds made available through an insurance policy, the Federal Emergency Management Agency (FEMA), a State, or a nonprofit relief organization, or any other third party. Grantees may use program funds to supplement funds from such sources up to the full amount needed for emergency assistance.

Use of funds for a purpose authorized under the HEA is subject to the regulations that pertain to that purpose. For example, if activities under a particular grant program or financial aid program were disrupted and require emergency aid to become fully operational, program funds for this purpose are subject to the regulations for that grant or aid program, except that any requirements relating to matching, Federal share, reservation of funds, or maintenance of effort under 20 U.S.C. 1087–51 *et seq.* or 1138 *et seq.* that would otherwise be applicable do not apply.

Information about the Federal Student Aid programs is available at studentaid.ed.gov/sa/. The U.S. Code version of the HEA is available at uscode.house.gov/view.xhtml?req=granuleid%3AUSC-prelim-title20-chapter28&edition=prelim.

4. *Compliance Assurance*: Applicants must provide an assurance that they will comply with all requirements that apply to the 2019 EAI Program, including but not limited to: Providing required certifications that all funds are expended on allowable activities; complying with reporting requirements; cooperating with any Inspector General inquiries; complying with applicable Office of Management and Budget assurances; and providing the required certification regarding restrictions on the use of funds for lobbying.

5. *Allocation Criteria*: The Secretary establishes the following factors as criteria that will be used in allocating these funds:

(a) *Total funds requested*. The amount of funds requested to remedy the effects of the covered disaster or emergency, including the uncovered costs for renovations, construction, and direct student services. Applicants should exclude any costs for which they have received or anticipate receiving reimbursement from other sources, including a Federal or other relief organization, to remedy the effects of the covered disaster or emergency.

Note: For direct student services applicants may only include those expenses directed to students who are homeless or at risk of becoming homeless, and applicants may not include expenses directed to a larger population of students, even if those expenses have aided some students who were homeless or at risk of becoming homeless. Applicants may, however, include expenses directed toward individual students who are homeless or at risk of becoming homeless, even if similar aid or services have been made available to other students.

(b) *Funds needed to serve students who are homeless or at risk of becoming homeless*. From the total disaster-related net expenses provided in (a), applicants should identify the funding needed to serve students who are homeless or at risk of becoming homeless.

(c) *Funds received*. Any amount of any insurance settlement or other funds received by the IHE, from any source including a Federal or other relief organization, to remedy the effects of the covered disaster or emergency.

6. *Risk Assessment and Specific Conditions*: Consistent with 2 CFR 200.205, before awarding grants under this program the Department conducts a review of the risks posed by applicants.

Under 2 CFR 3474.10, the Secretary may impose specific conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

7. *Additional Monitoring:* This program is designated as “susceptible to significant improper payments” for purposes of the Improper Payments Information Act of 2002 (31 U.S.C. 3321 note). See title VIII of the Disaster Supplemental, and Public Law 115–123, the Bipartisan Budget Act of 2018, division B, subdivision 1, title XII, § 21208(a), February 9, 2018, 132 Stat. 108. Consequently, if 2019 EAI Program grantees expend more than \$10,000,000 under this program—a level of expenditures that the Department anticipates will be met—there will be additional requirements for grantees under the program, including making expenditure information and documentation available for review by the Department. We will provide additional information about this requirement after we make awards, providing advanced notice to ensure grantees understand their responsibilities for documenting all expenditures of 2019 EAI Program funds. In general, these documentation requirements are identical to those ordinarily required for all Federal education program expenditures; the primary impact of the Improper Payments Information Act will be increased review of this documentation.

VI. Award Administration Information

1. *Award Notices:* If you receive a grant award under the 2019 EAI Program, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

2. *Reporting:* (a) If you apply for a grant under the program, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. The Secretary may also require more

frequent performance reports under 34 CFR 75.720(c).

3. *Performance Measure:* The Secretary has established the number of enrolled students receiving 2019 EAI Program funding as the performance measure for assessing the effectiveness of the 2019 EAI Program.

VII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to one of the persons listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at www.govinfo.gov. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or PDF. To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: www.federalregister.gov. Specifically, through the advanced feature at this site, you can limit your search to documents published by the Department.

Dated: September 11, 2019.

Robert L. King,

Assistant Secretary for the Office of Postsecondary Education.

[FR Doc. 2019–19941 Filed 9–13–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14981–000]

Lock+™ Hydro Friends Fund XXIX, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On March 6, 2019, Lock+™ Hydro Friends Fund XXIX, LLC, filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Curwensville Dam Hydropower Project to be located at the U.S. Army Corps of Engineers’ (Corps) Curwensville Dam on the West Branch

Susquehanna River in Tioga County, Pennsylvania. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners’ express permission.

The proposed project would consist of the following: (1) A new 30-foot-long, 30-foot-wide, 160-foot-high Large Frame Module; (2) two turbine-generator units with a total rated capacity of 1.5 megawatts; (3) a new 4-foot-long, 4-foot-wide, 3-foot-high pad-mounted transformer; (4) a new 300-foot-long, 13-kilovolt transmission line connecting the new transformer to an existing distribution line; and (5) appurtenant facilities. The proposed project would have an annual generation of 6,800 megawatt-hours.

Applicant Contact: Wayne Krouse, Lock+™ Hydro Friends Fund XXIX, LLC, P.O. Box 43796, Birmingham, AL 35243; phone: 877–556–6566 ext. 709.

FERC Contact: Woohee Choi; phone: (202) 502–6336.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications 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–14981–000.

More information about this project, including a copy of the application, can be viewed or printed on the “eLibrary” link of the Commission’s website at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (P–14981) in the docket number field to

access the document. For assistance, contact FERC Online Support.

Dated: September 10, 2019.

Kimberly D. Bose,
Secretary.

[FR Doc. 2019-19970 Filed 9-13-19; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12611-009]

Verdant Power, LLC; Notice of Request To Waive Requirement To File Draft License Application

a. *Type of Filing:* Request to Waive Pre-Filing Requirements.
b. *Project No.:* 12611-009.
c. *Date Filed:* August 30, 2019.
d. *Applicant:* Verdant Power, LLC.
e. *Name of Project:* Roosevelt Island Tidal Energy Project.
f. *Location:* On the East River in New York County, New York.
g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a-825r.
h. *Applicant Contact:* Mr. Ronald F. Smith, President and Chief Operating Officer, Verdant Power, LLC, P.O. Box 282, Roosevelt Island, New York, New York 10044. Phone: (703) 328-6841.
i. *FERC Contact:* Andy Bernick, (202) 502-8660, andrew.bernick@ferc.gov.
j. Verdant requests a waiver of the Commission's pre-filing regulations under section 16.8(c) with respect to the requirement to submit a draft license application for the Roosevelt Island Tidal Energy Project. Verdant states that the project has a long history of consultation and that it proposes no substantive changes to the currently submitted pilot project. Further, Verdant indicates that it held two joint agency meetings (on January 8, 2019 and May 16, 2019), the second of which was held for federal agencies that were unable to attend the January meeting due to the funding lapse at certain federal agencies between December 22, 2018, and January 25, 2019. Verdant explains that the second joint agency meeting and the additional time needed to respond to study requests has reduced the amount of time available for submitting and effectively reviewing responses to a draft license application, prior to the filing of the final license application by December 31, 2019. Therefore, Commission staff is soliciting comments on Verdant's request to waive the requirement to file a draft license application for the Roosevelt Island Tidal Energy Project, pursuant to

sections 16.8(c)(4) and 16.8(c)(6) of the Commission's regulations.

k. The deadline for filing comments is 15 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file motions to intervene and protests, comments, and final terms and conditions, recommendations, and prescriptions 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-12611-009.

l. A copy of the request is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll free at (866) 208-3676, or for TTY, contact (202) 502-8659. A copy is also available for inspection and reproduction at the address in item h above.

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, contact FERC Online Support.

Dated: September 10, 2019.

Kimberly D. Bose,
Secretary.

[FR Doc. 2019-19968 Filed 9-13-19; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14979-000]

Lock+™ Hydro Friends Fund XXVII, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On March 6, 2019, Lock+™ Hydro Friends Fund XXVII, LLC, filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act, proposing to study the feasibility of the Cowanesque Dam Hydropower Project to be located at the U.S. Army Corps of Engineers' Cowanesque Dam on the Cowanesque River in Tioga County, Pennsylvania. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following: (1) A new 30-foot-long, 30-foot-wide, 160-foot-high Large Frame Module; (2) two turbine-generator units with a total rated capacity of 0.85 megawatt; (3) a new 4-foot-long, 4-foot-wide, 3-foot-high pad-mounted transformer; (4) a new 200-foot-long, 13-kilovolt transmission line connecting the new transformer to an existing distribution line; and (5) appurtenant facilities. The proposed project would have an annual generation of 3,700 megawatt-hours.

Applicant Contact: Wayne Krouse, Lock+™ Hydro Friends Fund XXVII, LLC, P.O. Box 43796, Birmingham, AL 35243; phone: 877-556-6566 ext. 709.

FERC Contact: Woohee Choi; phone: (202) 502-6336.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications 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-14979-000.

More information about this project, including a copy of the application, can be viewed or printed on the “eLibrary” link of the Commission’s website at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (P-14979) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: September 10, 2019.

Kimberly D. Bose,
Secretary.

[FR Doc. 2019-19972 Filed 9-13-19; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12635-002]

Moriah Hydro Corporation; Notice of Technical Meeting

a. *Date and Time of Meeting:* Thursday, October 3, 2019 at 11:00 a.m. Eastern Daylight Time.

b. *Place:* New York State Department of Environmental Conservation, 625 Broadway, Albany, New York 12233-0001, and via telephone conference.

c. *FERC Contact:* Andy Bernick at andrew.bernick@ferc.gov, or (202) 502-8660.

d. *Purpose of Meeting:* Commission staff is participating in a technical meeting with the U.S. Fish and Wildlife Service (FWS), New York State Department of Environmental Conservation, and Moriah Hydro Corporation (Moriah Hydro) to discuss Endangered Species Act (ESA) consultation as it relates to licensing the proposed Mineville Energy Storage Project, to be constructed in the Town of Moriah, Essex County, New York. The proposed agenda will include discussions of: (1) The Commission’s hydro-licensing process and June 18, 2019, request to initiate formal consultation regarding the endangered Indiana bat and threatened northern long-eared bat; (2) the Commission’s draft environmental impact statement as the basis for the project’s biological

assessment, per FWS’ request; (3) the FWS’ request for additional information, filed July 17, 2019; (4) Moriah Hydro’s proposal to install a water control feature to regulate water levels within New Bed Mine; and (5) additional issues relating to ESA consultation.

e. A summary of the meeting will be prepared and filed in the Commission’s public file for the project.

f. All local, state, and federal agencies, Indian tribes, and other interested parties are invited to participate in-person or by telephone. However, as in-person seating is limited, priority will be given to parties directly involved in the ESA consultation process. Please contact Andy Bernick at andrew.bernick@ferc.gov, or (202) 502-8660 by September 23, 2019, to RSVP and to receive specific instructions on how to participate.

Dated: September 9, 2019.

Kimberly D. Bose,
Secretary.

[FR Doc. 2019-19955 Filed 9-13-19; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP19-506-000]

Tennessee Gas Pipeline Company, LLC; Notice of Request Under Blanket Authorization

Take notice that on August 30, 2019, Tennessee Gas Pipeline Company, LLC (Tennessee), 1001 Louisiana Street, Houston, Texas 77002, filed in the above referenced docket a prior notice request pursuant to sections 157.203, 157.205, and 157.216(b) of the Commission’s regulations under the Natural Gas Act and its blanket certificate issued in Docket No. CP82-413-000 for authorization to abandon an inactive injection/withdrawal well, designated as Well 5564, in the Hebron Storage Field (Field) located in Potter County, Pennsylvania. Specifically, Tennessee proposes to plug and abandon the well, abandon in place approximately 1,167 feet of six-inch related lateral pipeline, abandon by removal other related appurtenant facilities including the well head, and restore the well site. Tennessee states that the proposed abandonment of Well 5564 will not affect the capacity of the Field or the deliverability into or from the Field. Further, Tennessee states that the project will not abandon or decrease service to its customers. Tennessee estimates the cost of the project to be

\$550,000, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The filing may also be viewed on the web at <http://www.ferc.gov> using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll free at (866) 208-3676, or TTY, contact (202) 502-8659.

Any questions concerning this application may be directed to Ben J. Carranza, Director, Regulatory, Tennessee Gas Pipeline Company, LLC, 1001 Louisiana Street, Houston, Texas 77002, by telephone at (713) 420-5535, or by email at ben_carranza@kindermorgan.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 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 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 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.

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: September 9, 2019.

Kimberly D. Bose,
Secretary.

[FR Doc. 2019-19953 Filed 9-13-19; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14980-000]

Lock+™ Hydro Friends Fund XXVIII, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On March 6, 2019, Lock+™ Hydro Friends Fund XXVIII, LLC, filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Nockamixon Dam Hydropower Project to be located at the Pennsylvania Department of Conservation and Natural Resources' Nockamixon Dam on Tohickon Creek in Bucks County, Pennsylvania. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following: (1) A new 30-foot-long, 30-foot-wide, 160-foot-high Large Frame

Module; (2) two turbine-generator units with a total rated capacity of 0.8 megawatt; (3) a new 4-foot-long, 4-foot-wide, 3-foot-high pad-mounted transformer; (4) a new 300-foot-long, 13-kilovolt transmission line connecting the new transformer to an existing distribution line; and (5) appurtenant facilities. The proposed project would have an annual generation of 3,500 megawatt-hours.

Applicant Contact: Wayne Krouse, Lock+™ Hydro Friends Fund XXVIII, LLC, P.O. Box 43796, Birmingham, AL 35243; phone: 877-556-6566 ext. 709.

FERC Contact: Woohee Choi; phone: (202) 502-6336.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications 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-14980-000.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of the Commission's website at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (P-14980) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: September 10, 2019.

Kimberly D. Bose,
Secretary.

[FR Doc. 2019-19969 Filed 9-13-19; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD19-19-000]

Notice of Workshop; Grid-Enhancing Technologies

Take notice that the Federal Energy Regulatory Commission (Commission) will convene a staff-led workshop in the above-referenced proceeding on Tuesday and Wednesday, November 5-6, 2019 from approximately 8:45 a.m. to 5:00 p.m. Eastern time. The conference will be held at Commission headquarters, 888 First Street NE, Washington, DC 20426. Commissioners may attend and participate.

The purpose of this workshop is to discuss grid-enhancing technologies that increase the capacity, efficiency, or reliability of transmission facilities. Panelists and staff will discuss how grid-enhancing technologies are currently used in transmission planning and operations, the challenges to their deployment and implementation, and what the Commission can do regarding those challenges, including incentivizing or requiring the adoption of grid-enhancing technologies by utilities and RTOs/ISOs. These technologies include, but are not limited to: (1) Power flow control and transmission switching equipment; (2) storage technologies, and (3) advanced line rating management technologies. Participants at this workshop will include representatives from utilities, RTOs/ISOs, technology vendors, researchers, and other interested parties. Further details and a formal agenda will be issued prior to the conference.

The workshop will be open for the public to attend. Advance registration is not required to attend, but is encouraged. Attendees may register at the following web page: <http://www.ferc.gov/whats-new/registration/11-06-19-form.asp>. In-person attendees should allow time to pass through building security procedures before the start time of the workshop.

Those wishing to participate as a panel member in this conference should submit a nomination form online by 5:00 p.m. on September 20, 2019 at: <http://www.ferc.gov/whats-new/registration/11-06-19-speaker-form.asp>. At this web page, please provide an abstract of the issue(s) you propose to address. Due to time constraints, we may not be able to accommodate all those interested in being panelists. There will also be opportunity for audience participation.

The workshop will be transcribed and webcast. Transcripts will be available for a fee from Ace Reporting (202-347-3700). A link to the webcast of this event will be available in the Commission Calendar of Events at www.ferc.gov. The Capitol Connection provides technical support for the webcasts and offers the option of listening to the workshop via phone-bridge for a fee. For additional information, visit www.CapitolConnection.org or call (703) 993-3100.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to accessibility@ferc.gov or call toll free 1-866-208-3372 (voice) or 202-208-8659 (TTY), or send a fax to 202-208-2106 with the required accommodations.

For more information about this workshop, please contact Samin Peirovi at Samin.Peirovi@ferc.gov or (202) 502-8080. For information related to logistics, please contact Sarah McKinley at Sarah.Mckinley@ferc.gov or (202) 502-8368.

Dated: September 9, 2019.

Kimberly D. Bose,
Secretary.

[FR Doc. 2019-19954 Filed 9-13-19; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2019-0463; FRL 9999-83-OW]

Notice of Intent To Develop a Policy on the Determination of a Harmful Algal Bloom (HAB) and Hypoxia as an Event of National Significance in Freshwater Systems

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability; request for comments.

SUMMARY: The Environmental Protection Agency (EPA) is requesting public comment to inform the development of an Agency policy for determining if a harmful algal bloom (HAB) or hypoxia event in freshwater is an “event of national significance.” Recent amendments to the Harmful Algal Bloom and Hypoxia Research and Control Act (HABHRCA), provide the EPA with the statutory authority to make such a determination in the case of a freshwater HAB or hypoxia event. Public comments are intended to inform the development of a policy for the EPA

to make such determinations, specifically for events in freshwater. A federal determination that such an occurrence is an event of national significance enables mobilization of federal resources to assess and mitigate its detrimental effects, subject to the availability of appropriations. The EPA requests input on what the Agency should specifically consider for determining a “HAB or Hypoxia event of national significance” in freshwater, and related factors in order to inform development of a draft EPA policy. On July 25, 2019, the National Oceanic and Atmospheric Administration (NOAA) issued a separate notice to solicit comments on HAB or hypoxia events of national significance in marine and coastal waters.

DATES: Comments must be received on or before October 31, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OW-0463 to the *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. 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, 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/commentingepa-dockets>.

FOR FURTHER INFORMATION CONTACT: Dr. Lesley V. D’Anglada, Health and Ecological Criteria Division, Office of Water (Mail Code 4304T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 566-1125; email address: danglada.lesley@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

How can I get copies of this document and other related information?

1. **Docket.** The EPA has established a docket for this action under Docket ID No. EPA-HQ-OW-0463. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Water Docket is (202) 566-2426.

2. **Electronic Access.** You may access this **Federal Register** document electronically from the Government Printing Office under the “**Federal Register**” listings FDsys (<http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR>).

II. What are harmful algal blooms (HABs) and hypoxia and why is the EPA concerned about them?

Harmful algal blooms (HABs) are caused by certain types of photosynthetic organisms that under certain conditions form large accumulations of algae that can adversely affect human health and the environment and can cause local economic losses. In freshwater, cyanobacteria are the major HABs-forming taxon. Cyanobacteria are microorganisms that can produce harmful *cyanotoxins* that, if ingested in sufficient amounts, can kill fish, shellfish, livestock, wildlife, and adversely impact human health. Algal blooms, both those that produce cyanotoxins and those that do not, can also harm aquatic environments by depleting oxygen needed to sustain freshwater aquatic life. HABs can negatively impact drinking water systems, recreation, commercial and recreational fishing, property values and public health. Recent notable drinking water cyanotoxin-related events include the 2018 HAB event in Detroit Lake, Oregon, that resulted in do not drink advisories in the City of Salem, and the 2014 HAB event on Lake Erie that resulted in do not drink advisories in the City of Toledo. In 2016, a cyanobacteria bloom in Lake Okeechobee traveled into St. Lucie Estuary, resulting in the largest cyanobacterial bloom reported in the state of Florida in ten years. The bloom

in the St. Lucie River resulted in beach closures and economic losses.

Hypoxia is a condition where the concentration of dissolved oxygen (DO) in a portion of the water column decreases to a level that can no longer support aquatic life, typically less than 2–3 milligrams DO per liter. A variety of factors cause low or zero oxygen conditions in waterbodies, including nitrogen and phosphorus pollution, and waterbody stratification, or layering, due to temperature gradients. Low dissolved oxygen conditions are a serious environmental concern that can impact valuable fisheries and disrupt sensitive ecosystems. In freshwater lakes, hypoxia in deeper waters coupled with warm shallow waters can severely limit the habitat available for fish species, such as trout. Exposure to hypoxia can cause adverse effects to aquatic life, such as reduced growth and reproduction. For more details on HABs, please refer to this site: <https://www.epa.gov/cyanohabs>, and for more information on Hypoxia, please refer to this site: <https://www.epa.gov/ms-htf/hypoxia-101>.

III. Information on the Harmful Algal Bloom and Hypoxia Research and Control Act

In 1998, Congress recognized the severity of these threats and passed the Harmful Algal Bloom and Hypoxia Research and Control Act (HABHRCA 1998, Pub. L. 105–383). The Harmful Algal Bloom and Hypoxia Research and Control Amendments Act of 2004 (HABHRCA 2004, Pub. L. 108–456) and 2014 (HABHRCA 2014, Pub. L. 113–124) reaffirmed and expanded the mandate for NOAA to advance the scientific understanding and ability to detect, monitor, assess, and predict HAB and hypoxia events. Congress most recently reauthorized and amended HABHRCA through the National Integrated Drought Information System Reauthorization Act of 2018 (Pub. L. 115–423, § 9). This most recent reauthorization and amendment of HABHRCA is referred to as the Harmful Algal Bloom and Hypoxia Research and Control Amendments Act of 2017 (HABHRCA 2017). HABHRCA 2017 provides NOAA and EPA with authority to make a determination of a “HAB or hypoxia event of national significance,” for marine or coastal events or freshwater events, respectively, either in the discretion of the Agency head or at the request of a Governor of an affected state (33 U.S.C. 4010). Following such a determination, federal officials may “make sums available to the affected State or local government for the purposes of assessing and mitigating the

detrimental environmental, economic, subsistence use, and public health effects of the event of national significance.” Funds would be subject to the availability of appropriations, though either of the respective agencies may accept donations of funds, services, facilities, materials, or equipment determined necessary for the purpose of assessing and mitigating the detrimental effects, and donated funds may be expended without further appropriation and without fiscal year limitation. As directed under HABHRCA 2017, EPA, in coordination with NOAA, intends to develop a policy for determining a HAB or Hypoxia occurrence as an “event of national significance” in freshwater systems in the United States. NOAA issued a separate notice to solicit comments on marine and coastal hypoxia or HAB events in 84 FR 35854 on July 25, 2019. After consideration of comments on this notice, the EPA anticipates developing a draft policy for which the Agency would solicit further comment.

HABHRCA 2017 identified the following six factors to be considered in making the determination of a “HAB or hypoxia event of national significance:” the toxicity of the harmful algal bloom; the severity of the hypoxia; its potential to spread; the economic impact; the relative size in relation to the past five occurrences of harmful algal blooms or hypoxia events that occur on a recurrent or annual basis; and the geographic scope, including the potential to affect several municipalities, to affect more than one state, or to cross an international boundary.

IV. Solicitation of Public Comments

The EPA is soliciting public comments regarding the factors provided by the amendments for the EPA to determine a HAB or Hypoxia Event of National Significance in freshwater systems. The EPA requests separate comment on the application of those factors for HAB and hypoxia events as it is likely that the factors would be considered differently for the different types of events. Specifically, the EPA is soliciting public comments on how to define, quantify, and weigh the following statutory parameters:

A. Toxicity of the harmful algal bloom—What metrics should the EPA use to assess toxicity in determining national significance? For example, should the EPA consider reports of human or animal illnesses or deaths, or adverse effects on aquatic life? Are there other relevant metrics the EPA should consider? Should the toxicity of the event be considered differently based on its frequency and duration?

B. Severity of hypoxia—What metrics should the EPA use to determine whether the severity of a hypoxic event makes it nationally significant? For example, should the severity of the event include consideration of human health, economic, and environmental impacts? Are there other relevant metrics the EPA should consider?

C. Potential to spread—What metrics should the EPA use in determining whether the potential for the spread of a HAB or hypoxia event makes it nationally significant? For example, should historical information be used to inform a decision on the potential for a HAB or hypoxia event to spread? Are there other relevant metrics the EPA should consider?

D. Economic impact—What metrics should the EPA use for economic impact in determining national significance? For example, should economic status (*i.e.*, make-up of the state, local, and tribal government economy and its reliance on the affected waterway for tourism or drinking water) be considered when determining the national significance of an event? If so, how should economic status be considered? Are there other relevant metrics the EPA should consider?

E. Relative size of an event in relation to the past 5 occurrences of HABs or hypoxia events that occur on a recurrent or annual basis—What metrics should the EPA use for recurrence in determining national significance, and specifically whether the size and scope of an event or occurrence is significant relative to past events? For example, should the EPA assign a specific number of years, seasons, or months between events in considering national significance? Are there other relevant metrics the EPA should consider?

F. Geographic scope, including the potential to affect several municipalities, to affect more than one state, or to cross an international boundary—What metrics should the EPA use in determining whether the geographic scope of a HAB or hypoxia event is nationally significant? For example, for an event that has or might impact more than one state should the EPA make a single determination for that event applicable to all states impacted including those states that may be impacted by expansion, movement, or intensification of the event? Should the EPA limit its consideration of national significance to the area requested by a state based on the then-current location and geographic extent of the event?

The EPA is also requesting comments on whether the Agency should consider developing additional criteria and

whether to establish specific procedures for making such determinations. For example:

A. Should the EPA consider the state's access to critical resources (human, financial, and infrastructure) in determining national significance? For example, does the state have access to technical expertise, necessary supplies/equipment, and alternate sources of water? If the EPA considers such access, what metrics should the EPA use to measure the capacity of state and local or tribal governments to address the bloom event?

B. Should the EPA consider certain factors when an event impacts or threatens drinking water sources or finished drinking water? How should duration, magnitude, frequency, extent, and toxicity of HAB impacts on drinking water supplies be considered in determining events of national significance?

C. Should the EPA consider certain factors when an event has impacts on or threatens recreational waters? How should these impacts be weighed in determining national significance?

D. Should a determination of national significance be made only if funding has been appropriated to the agencies? If two or more states request determinations, and the determinations of national significance would otherwise qualify each state for funding consistent with the factors considered in making the determination, but only limited funds are available, how should amounts be distributed? Should the funding be equally proportioned or distributed according to some sort of a relative rank or score derived from a weighting of factors considered in the determination of national significance?

E. What information should an impacted state provide to the EPA when requesting a determination of a freshwater event of national significance or a request to make sums available to the impacted state or local government to assess and mitigate an event of national significance?

F. Should the EPA consider whether a state or local government that requests a determination that a HAB or hypoxia is an event of national significance concurrently requests other Federal relief for the same event or occurrence? If so, how should the EPA prioritize funding, for example, based on consideration of a particular factor or multiple factors?

G. Should the EPA require that an affected state or local government request a determination of a freshwater event of national significance within certain timeframes with respect to the start or end of the event or occurrence?

H. Other than funds, what tools and methods should the EPA make available after a determination of a freshwater event of national significance is made?

Dated: September 6, 2019.

David P. Ross,

Assistant Administrator, Office of Water.

[FR Doc. 2019-19985 Filed 9-13-19; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9998-92-OMS]

Good Neighbor Environmental Board

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Public Federal Advisory Committee Teleconference.

SUMMARY: Pursuant to the Federal Advisory Committee Act, Public Law 92-463, notice is hereby given that the Good Neighbor Environmental Board (Board) will hold a public teleconference on September 19, 2019 from 12:00 p.m.-4:00 p.m. Eastern Daylight Time. Due to unforeseen administrative circumstances, EPA is announcing this teleconference with less than 15 calendar days' notice. For further information regarding the teleconference and background materials, please contact Ann-Marie Gantner at the number and email provided below.

Background: The Good Neighbor Environmental Board is a federal advisory committee chartered under the Federal Advisory Committee Act, Public Law 92-463. By statute, the Board is required to submit an annual report to the President on environmental and infrastructure issues along the U.S. border with Mexico.

Purpose of Meeting: The purpose of this teleconference is to discuss and approve the Board's Nineteenth Report to the President, which focuses on energy infrastructure along the U.S.-Mexico border.

General Information: The agenda and teleconference materials, as well as general information about the Board, can be found at <http://www2.epa.gov/faca/gneb>. If you wish to make oral comments or submit written comments to the Board, please contact Ann-Marie Gantner at least five days prior to the teleconference.

Meeting Access: For information on access or services for individuals with disabilities, please contact Ann-Marie Gantner at (202) 564-4330 or email at gantner.ann-marie@epa.gov. To request accommodation of a disability, please

contact Ann-Marie Gantner at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

Dated: August 15, 2019.

Ann-Marie Gantner,

Program Analyst.

[FR Doc. 2019-19983 Filed 9-13-19; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2019-0174; FRL 9999-82-OW]

Draft National Water Reuse Action Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability; request for comments.

SUMMARY: The Environmental Protection Agency (EPA) is requesting public comment on a draft *National Water Reuse Action Plan*. This draft Action Plan seeks to foster greater consideration of water reuse across the water sector, such as agriculture, industry, potable water and more. Safe and reliable water supplies for human consumption, agriculture, business, industry, recreation, and healthy ecosystems are critical to our Nation's communities and economy. The draft Action Plan describes how agriculture, industry, and communities have demonstrated the value of reusing water, largely in response to various forms of water crises such as drought or source water contamination. Water reuse can improve the security, sustainability, and resilience of our Nation's water resources, especially when considered at the watershed or basin scale, through integrated and collaborative water resource planning.

To accelerate the consideration of water reuse approaches and build on existing science, research, policy, technology, and both national and international experiences, the EPA has facilitated development of this draft *National Water Reuse Action Plan* across the water sector and with federal, state, and tribal partners. The draft Action Plan is intended to seek commitments and drive action across the various stakeholder groups and the Nation. The plan consists of 46 proposed actions that support consideration and implementation of water reuse applications across ten strategic objectives.

This action is part of a larger effort by the Administration to better coordinate and focus taxpayer resources on some of

the Nation's most challenging water resource concerns, including ensuring water availability and mitigating the risks posed by droughts.

DATES: Comments must be received on or before December 16, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OW-0174 to the *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. 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, 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/commentingepa-dockets>.

FOR FURTHER INFORMATION CONTACT: John Ravenscroft, Office of Science and Technology, Office of Water (Mail Code 3207A), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 566-1101; email address: ravenscroft.john@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

How can I get copies of this document and other related information?

1. *Docket.* The EPA has established a docket for this action under Docket ID No. EPA-HQ-OW-0174. Publicly available docket materials are available electronically through www.regulations.gov, posted online on the EPA's water reuse website (www.epa.gov/waterreuse/water-reuse-action-plan) or in hard copy at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Avenue NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is

(202) 566-1744, and the telephone number for the Water Docket is (202) 566-2426.

2. *Electronic Access.* You may access this **Federal Register** document electronically from the Government Printing Office under the "**Federal Register**" listings FDsys (<http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR>).

II. Why develop a water reuse action plan?

Clean, safe, and reliable water supplies for human consumption, agriculture, business, recreation, and healthy ecosystems are critical to our Nation's communities and economy. Due to various pressures, it is reported that 40 states anticipate some freshwater shortages in the next decade. Communities, agriculture, and businesses are looking to diversify their water supply portfolios to meet current and future needs. Water reuse (also known as recycled or reclaimed water) represents a major opportunity to supplement existing water supplies from potential sources for reuse from industrial process water, agricultural return flows, municipal wastewater, oil and gas produced water, and stormwater, when these potential sources are appropriately and effectively treated to meet "fit for purpose specifications" including appropriate public health and environmental needs.

The goal of the draft Action Plan is to better coordinate and focus taxpayer resources on some of the Nation's most challenging water resource concerns, including ensuring water availability and mitigating the risks posed by droughts. The draft Action Plan contains key actions identified by stakeholders across the water reuse sector that can help improve water security, sustainability, and resilience.

III. Summary of Water Reuse Action Plan Contents

The draft *National Water Reuse Action Plan* is approximately 45 pages in length and is supported by extensive information in nine Appendices. Section 1 of the draft Action Plan frames the business case for water reuse including: Key definitions; summary of the key drivers, opportunities, and challenges for water reuse; the potential sources and applications for water reuse; and guiding principles and the methodology for development of the draft Action Plan.

Section 2 of the draft Action Plan identifies 46 proposed actions across the following ten strategic objectives:

1. Enable consideration of water reuse with integrated and collaborative action at the watershed scale.

2. Coordinate and integrate federal, state, tribal, and local water reuse programs and policies.

3. Compile and refine fit-for-purpose specifications.

4. Promote technology development, deployment, and validation.

5. Improve availability of water information.

6. Facilitate financial support of water reuse.

7. Integrate and coordinate research on water reuse.

8. Improve outreach and communication on water reuse.

9. Support a talented and dynamic workforce.

10. Develop water reuse metrics that support goals and measure progress.

As explained in the methodology, these proposed actions were identified from the following sources:

1. Analysis and summary of the water reuse literature (greater than 150 sources).

2. Outreach and dialogue with an estimated 2,300 participants.

3. Public input submitted to the first public docket on the plan (opened for April 18, 2019 until July 1, 2019).

4. WaterReuse Association expert convening report (conducted in Spring 2019).

5. Review of international experiences with water reuse.

6. Review of water reuse case studies from relevant applications throughout the United States.

Section 3 of the draft Action Plan describes the process for going forward to identify the highest priority actions and seeks leaders and collaborators to describe and commit to specific actions.

IV. Solicitation of Public Comments

The draft plan and the associated appendices can be found at: www.epa.gov/waterreuse/water-reuse-action-plan. The EPA is soliciting public comments to inform revisions to proposed actions, as well as to identify their implementation steps and milestones and the collaborators who may carry out those actions. In addition to providing general input, commenters are encouraged to:

- Identify the most important actions they feel should be taken in the near term.

- Identify and describe the specific attributes and characteristics of the actions that will achieve success.

- Identify critical implementation steps and milestones necessary to successfully implement the proposed actions.

- Commit to lead or collaborate with others on implementing any of the proposed actions.

- Provide additional information or recommendations to inform these or other proposed actions.

The goal is to issue a final Action Plan that includes clear commitments and milestones for actions that will further water reuse to help ensure the sustainability, security, and resilience of the Nation's water resources.

Dated: September 6, 2019.

David P. Ross,

Assistant Administrator, Office of Water.

[FR Doc. 2019-19984 Filed 9-13-19; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Submission for OMB Review; Comment Request (OMB No. 3064-0188)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Agency information collection activities: submission for OMB review; comment request.

SUMMARY: The FDIC, as part of its obligations under the Paperwork

Reduction Act of 1995, invites the general public and other Federal agencies to take this opportunity to comment on the renewal of the existing information collection described below (3064-0188) on July 16, 2019, the FDIC requested comment for 60 days on a proposal to renew the information collection described below. No comments were received. The FDIC hereby gives notice of its plan to submit to OMB a request to approve the renewal of this collection, and again invites comment on this renewal.

DATES: Comments must be submitted on or before October 16, 2019.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- <https://www.FDIC.gov/regulations/laws/federal>.

- *Email:* comments@fdic.gov. Include the name and number of the collection in the subject line of the message.

- *Mail:* Manny Cabeza (202-898-3767), Counsel, MB-3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT:

Manny Cabeza, Counsel, 202-898-3767, mcabeza@fdic.gov, MB-3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: On July 16, 2019, the FDIC requested comment for 60 days on a proposal to renew the information collection described below. No comments were received. The FDIC hereby gives notice of its plan to submit to OMB a request to approve the renewal of this collection, and again invites comment on this renewal.

Proposal to renew the following currently approved collection of information:

1. *Title:* Appraisal for Higher-Priced Mortgage Loans.

OMB Number: 3064-0188.

Form Number: None.

Affected Public: Insured state nonmember banks and state savings associations.

Burden Estimate:

SUMMARY OF ANNUAL BURDEN AND INTERNAL COST

Information collection (IC) description	Type of burden	Obligation to respond	Estimated number of respondents	Estimated frequency of responses	Estimated time per response (hours)	Frequency of response	Total annual estimated burden (hours)
Review and Provide Copy of Full Interior Appraisal.	Third Party Disclosure.	Mandatory	1,300	13	0.14	On Occasion ..	2,366
Investigate and Verify Requirement for Second Appraisal.	Recordkeeping	Mandatory	1,300	8	0.14	On Occasion ..	1,456
Conduct and Provide Second Appraisal.	Third Party Disclosure.	Mandatory	1,300	1	0.14	On Occasion ..	182
Total Estimated Annual Burden							4,004

General Description of Collection

Section 1471 of the Dodd-Frank Act established a new Truth in Lending (TILA) section 129H, which contains appraisal requirements applicable to higher-risk mortgages and prohibits a creditor from extending credit in the form of a higher-risk mortgage loan to any consumer without meeting those requirements. A higher-risk mortgage is defined as a residential mortgage loan secured by a principal dwelling with an annual percentage rate (APR) that exceeds the average prime offer rate (APOR) for a comparable transaction as of the date the interest rate is set by certain enumerated percentage point spreads. The rule requires that, within

three days of application, a creditor provide a disclosure that informs consumers regarding the purpose of the appraisal, that the creditor will provide the consumer a copy of any appraisal, and that the consumer may choose to have a separate appraisal conducted at the expense of the consumer. If a loan meets the definition of a higher-risk mortgage loan, then the creditor would be required to obtain a written appraisal prepared by a certified or licensed appraiser who conducts a physical visit of the interior of the property that will secure the transaction, and send a copy of the written appraisal to the consumer. To qualify for the safe harbor provided under the rule, a creditor is required to review the written appraisal as specified

in the text of the rule and appendix A. If a loan is classified as a higher-risk mortgage loan that will finance the acquisition of the property to be mortgaged, and the property was acquired within the previous 180 days by the seller at a price that was lower than the current sale price, then the creditor is required to obtain an additional appraisal. A creditor is required to provide the consumer a copy of the appraisal reports performed in connection with the loan, without charge, at least days prior to consummation of the loan.

There is no change in the method or substance of the collection. The overall reduction in burden hours is the result of economic fluctuation. In particular,

the number of respondents has decreased while the hours per response and frequency of responses have remained the same.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, 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. All comments will become a matter of public record.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on September 11, 2019.

Valerie Best,

Assistant Executive Secretary.

[FR Doc. 2019-19927 Filed 9-13-19; 8:45 am]

BILLING CODE 6714-01-P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Termination of Receiverships

The Federal Deposit Insurance Corporation (FDIC or Receiver), as Receiver for each of the following insured depository institutions, was charged with the duty of winding up the affairs of the former institutions and liquidating all related assets. The Receiver has fulfilled its obligations and made all dividend distributions required by law.

NOTICE OF TERMINATION OF RECEIVERSHIPS

Fund	Receivership name	City	State	Termination date
10034	County Bank	Merced	CA	9/1/2019
10144	Home Federal Savings Bank	Detroit	MI	9/1/2019
10191	Bank of Illinois	Normal	IL	9/1/2019
10307	First Vietnamese American Bank	Westminster	CA	9/1/2019
10332	Evergreen State Bank	Stoughton	WI	9/1/2019
10523	Harvest Community Bank	Pennsville	NJ	9/1/2019

The Receiver has further irrevocably authorized and appointed FDIC-Corporate as its attorney-in-fact to execute and file any and all documents that may be required to be executed by the Receiver which FDIC-Corporate, in its sole discretion, deems necessary, including but not limited to releases, discharges, satisfactions, endorsements, assignments, and deeds. Effective on the termination dates listed above, the Receiverships have been terminated, the

Receiver has been discharged, and the Receiverships have ceased to exist as legal entities.

Authority: 12 U.S.C. 1819.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on September 11, 2019.

Valerie Best,

Assistant Executive Secretary.

[FR Doc. 2019-19926 Filed 9-13-19; 8:45 am]

BILLING CODE 6714-01-P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of Intent To Terminate Receivership

Notice is hereby given that the Federal Deposit Insurance Corporation (FDIC or Receiver) as Receiver for the institution listed below intends to terminate its receivership for said institution.

NOTICE OF INTENT TO TERMINATE RECEIVERSHIP

Fund	Receivership name	City	State	Date of appointment of receiver
4382	Citytrust	Bridgeport	CT	08/09/1991

The liquidation of the assets for the receivership has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing, identify the receivership to which the

comment pertains, and sent within thirty days of the date of this notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Authority: 12 U.S.C. 1819.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on September 9, 2019.

Valerie Best,

Assistant Executive Secretary.

[FR Doc. 2019-19924 Filed 9-13-19; 8:45 am]

BILLING CODE 6714-01-P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of Intent To Terminate Receivership

Notice is hereby given that the Federal Deposit Insurance Corporation (FDIC or Receiver) as Receiver for the institution listed below intends to

terminate its receivership for said institution.

NOTICE OF INTENT TO TERMINATE RECEIVERSHIP

Fund	Receivership name	City	State	Date of appointment of receiver
10512	Capitol City Bank & Trust Company	Atlanta	GA	02/13/2015

The liquidation of the assets for the receivership has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing, identify the receivership to which the comment pertains, and sent within thirty days of the date of this notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Authority: 12 U.S.C. 1819

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on September 11, 2019.

Valerie Best,

Assistant Executive Secretary.

[FR Doc. 2019-19925 Filed 9-13-19; 8:45 am]

BILLING CODE 6714-01-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 (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 notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than October 7, 2019.

A. Federal Reserve Bank of St. Louis (David L. Hubbard, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166-2034. Comments can also be sent electronically to *Comments.applications@stls.frb.org*:

1. *The Merkel Revocable Trust, Robert J. Merkle Sr. and Sarah E. Merkle as co-trustees, all of El Dorado, Arkansas;* individually and as part of a family control group that also includes the Robert J. Merkle Insurance Trust, Robert J. Merkle, Jr. as trustee, the Robert J. Merkle Stock Trust, Robert J. Merkle, Jr. as trustee, all of Dallas, Texas; and Margaret A. Merkle Niel, individually and as UTMA voting custodian for Elizabeth Tyler Niel, both of El Dorado, Arkansas, to retain voting shares of First Financial Banc Corporation, parent holding company of First Financial Bank, both of El Dorado, Arkansas.

Board of Governors of the Federal Reserve System, September 11, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019-19988 Filed 9-13-19; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

Granting of Requests for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register**.

The following transactions were granted early termination—on the dates indicated—of the waiting period provided by law and the premerger notification rules. The listing for each transaction includes the transaction number and the parties to the transaction. The grants were made by the Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period.

EARLY TERMINATIONS GRANTED AUGUST 1, 2019 THRU AUGUST 31, 2019

08/02/2019

20191445	G	Sonoco Products Company; MDCP VII—A Global Investments LP; Sonoco Products Company.
20191715	G	Ontario Power Generation Inc.; ISQ Hydro Aggregator LLC; Ontario Power Generation Inc.
20191716	G	One Rock Capital Partners II, LP; Actuant Corporation; One Rock Capital Partners II, LP.
20191721	G	Tinicum L.P.; Platte River Ventures II, L.P.; Tinicum L.P.
20191722	G	The Baring Asia Private Equity Fund VII, L.P.; CitiusTech Healthcare Technology Private Limited; The Baring Asia Private Equity Fund VII, L.P.

EARLY TERMINATIONS GRANTED AUGUST 1, 2019 THRU AUGUST 31, 2019—Continued

20191726	G	Etsy, Inc.; David A. Kalt; Etsy, Inc.
20191729	G	Dot Family Holdings, LLC; The 2015 Siegfried Family Trust; Dot Family Holdings, LLC.
20191730	G	AEA Investors Fund VII LP; Big Jack Ultimate Holdings LP; AEA Investors Fund VII LP.
20191745	G	Aquiline Financial Services Fund IV L.P.; North Haven CA Aggregator, LLC; Aquiline Financial Services Fund IV L.P.
20191746	G	CIP Capital Fund II, L.P.; Stephen Anderson; CIP Capital Fund II, L.P.
08/05/2019		
20191734	G	Twin River Worldwide Holdings, Inc.; Eldorado Resorts, Inc.; Twin River Worldwide Holdings, Inc.
20191736	G	MIP IV US REIT AIV LP; Riva Capital Partners III, L.P.; MIP IV US REIT AIV LP.
20191737	G	Silver Lake Alpine, L.P.; PSG PS Co-Investors L.P.; Silver Lake Alpine, L.P.
20191739	G	Blackstone Capital Partners VII L.P.; Vungle, Inc.; Blackstone Capital Partners VII L.P.
08/06/2019		
20190526	G	Boston Scientific Corporation; BTG plc; Boston Scientific Corporation.
20191705	G	Sierra Pacific Land & Timber Company; Fruit Growers Supply Company; Sierra Pacific Land & Timber Company.
20191720	G	Temasek Holdings (Private) Limited; RRJ Management (HK) Limited; Temasek Holdings (Private) Limited.
20191738	G	Gilead Sciences, Inc.; Galapagos NV; Gilead Sciences, Inc.
20191740	G	Synthomer plc; OMNOVA Solutions Inc.; Synthomer plc.
20191742	G	Callon Petroleum Company; Carrizo Oil & Gas, Inc.; Callon Petroleum Company.
20191744	G	Letterone Investment Holdings S.A.; Infiana Investment S.a.r.l.; Letterone Investment Holdings S.A.
20191747	G	TA XIII-A, L.P.; Lightyear Fund III AIV-3, L.P.; TA XIII-A, L.P.
20191760	G	Zoetis Inc.; Susan Herthel; Zoetis Inc.
08/07/2019		
20191749	G	Zoetis Inc.; Mark Herthel; Zoetis Inc.
08/08/2019		
20191669	G	NorthShore University HealthSystem; The Evangelical Covenant Church; NorthShore University HealthSystem.
08/09/2019		
20191637	G	James A. Ratcliffe; Ashland Global Holdings Inc.; James A. Ratcliffe.
20191708	G	CIP Capital Fund II, L.P.; Anthony J. DiBarnaba; CIP Capital Fund II, L.P.
20191723	G	Chamath Paliapitiya; Richard Branson; Chamath Paliapitiya.
20191724	G	Chamath Paliapitiya; Richard Branson; Chamath Paliapitiya.
20191748	G	Piper Jaffray Companies; SOP Holdings, LLC; Piper Jaffray Companies.
20191758	G	Sentinel Capital Partners VI, L.P.; Shawn M. Garber, M.D.; Sentinel Capital Partners VI, L.P.
20191762	G	Koch Industries, Inc.; Ibotta, Inc.; Koch Industries, Inc.
20191763	G	ICH Investment Holdings, L.P.; InnovaCare, Inc.; ICH Investment Holdings, L.P.
20191764	G	Ally Financial Inc.; Credit Services Corporation, LLC; Ally Financial Inc.
20191765	G	Kjeld Kirk Kristiansen; Merlin Entertainments plc; Kjeld Kirk Kristiansen.
20191766	G	Softbank Group Corp.; Berkshire Grey, Inc.; Softbank Group Corp.
20191768	G	Capgemini SE; Altran Technologies S.A.; Capgemini SE.
20191769	G	PPG Industries, Inc.; Sverica International Investment Fund III, L.P.; PPG Industries, Inc.
20191775	G	Blue Point Capital Partners IV, L.P.; Denis B. Brady; Blue Point Capital Partners IV, L.P.
20191781	G	Yellow Wood Capital Partners II, L.P.; Bayer AG; Yellow Wood Capital Partners II, L.P.
20191782	G	Stratose Aggregator, L.P.; Columbus Capital III, LLC; Stratose Aggregator, L.P.
20191784	G	Columbus Capital III, LLC; Stratose Aggregator, L.P.; Columbus Capital III, LLC.
20191788	G	Apax Digital L.P.; Pamlico Capital III, LP; Apax Digital L.P.
20191789	G	Providence Equity Partners VIII-A L.P.; Jorge Ellis; Providence Equity Partners VIII-A L.P.
08/12/2019		
20191776	G	ACM Fund II, LLC; Stanley A. Firestone; ACM Fund II, LLC.
08/13/2019		
20191774	G	New Jersey Resources Corporation; Riverstone Global Energy and Power Fund V (FT), L.P.; New Jersey Resources Corporation.
08/15/2019		
20191699	G	Roper Technologies, Inc.; Robert D. Mattlin; Roper Technologies, Inc.
08/16/2019		
20191770	G	Gerald W. Schwartz; WestJet Airlines Ltd.; Gerald W. Schwartz.
20191771	G	IBW Industriebeteiligungen Worms GmbH & Co. KGKG; JM Holding GmbH & Co. KGaA; IBW Industriebeteiligungen Worms GmbH & Co. KGKG.
20191772	G	Anja Fischer; JM Holding GmbH & Co. KGaA; Anja Fischer.
20191793	G	Adventist Health System/West; Daniel Buettner; Adventist Health System/West.

EARLY TERMINATIONS GRANTED AUGUST 1, 2019 THRU AUGUST 31, 2019—Continued

20191803	G	Jollibee Foods Corporation; Newco LLC; Jollibee Foods Corporation.
20191804	G	EQT Camera Side Car (No.1) SCSP; Bison Parent, LLC; EQT Camera Side Car (No.1) SCSP.
20191805	G	Entrepreneurial Equity Partners Fund I, L.P.; Vlado and Flavia Dukcevic; Entrepreneurial Equity Partners Fund I, L.P.
20191808	G	Kuvare Holdings LP; RL LP; Kuvare Holdings LP.
20191812	G	Sterling Investment Partners III, L.P.; Great Range Capital Fund I, L.P.; Sterling Investment Partners III, L.P.
20191813	G	Pernod Ricard S.A.; Firestone & Robertson Spirits, LLC; Pernod Ricard S.A.
20191814	G	HGGC Fund III-A, L.P.; Monotype Imaging Holdings Inc.; HGGC Fund III-A, L.P.
20191821	G	BCEC—GW Holdings (Guernsey) L.P.; Honos Luxembourg Holdings S.a.r.l.; BCEC—GW Holdings (Guernsey) L.P.
20191822	G	Tailwind Capital Partners III, L.P.; STG IV (Cayman), L.P.; Tailwind Capital Partners III, L.P.
20191824	G	CVC Capital Partners VII (A) L.P.; BBA Aviation plc; CVC Capital Partners VII (A) L.P.
20191825	G	Bain Capital Europe Fund V, SCSP; WPP plc; Bain Capital Europe Fund V, SCSP
20191827	G	New Mountain Partners V, L.P.; Arlington Capital Partners III, L.P.; New Mountain Partners V, L.P.

08/19/2019

20191807	G	Roper Technologies, Inc.; iPipeline Holdings, Inc.; Roper Technologies, Inc.
20191816	G	Orion US Holdings 1 L.P.; AltaGas Ltd.; Orion US Holdings 1 L.P.

08/20/2019

20190659	G	Nexstar Media Group, Inc.; Tribune Media Company; Nexstar Media Group, Inc.
20191790	G	New Mountain Partners V (AIV-D), L.P.; Tracy A. Wade; New Mountain Partners V (AIV-D), L.P.
20191791	G	New Mountain Partners V (AIV-D), L.P.; Linda M. Fotheringill; New Mountain Partners V (AIV-D), L.P.
20191826	G	Genstar Capital Partners IX, L.P.; Worldwide Facilities Holdings, LLC; Genstar Capital Partners IX, L.P.

08/23/2019

20191829	G	CVC Capital Partners VII (A) L.P.; Robert Bosch Industrietreuhand KG; CVC Capital Partners VII (A) L.P.
20191834	G	Assured Guaranty Ltd.; Affiliated Managers Group, Inc.; Assured Guaranty Ltd.
20191835	G	Genstar Capital Partners IX, L.P.; Primus Capital Fund VII, LP; Genstar Capital Partners IX, L.P.
20191837	G	Eurazeo SE; Thoma Bravo Discover Fund, L.P.; Eurazeo SE.
20191838	G	Genstar IX AIV, L.P.; Providence Equity Partners VII OEConnection L.P.; Genstar IX AIV, L.P.
20191840	G	Fox Corporation; Credible Labs Inc.; Fox Corporation.
20191841	G	TPG Growth III (A), L.P.; Larry J. Courtnage; TPG Growth III (A), L.P.
20191842	G	Windjammer Senior Equity Fund V, L.P.; BP HH Holdings LLC; Windjammer Senior Equity Fund V, L.P.
20191843	G	The Cheesecake Factory Incorporated; Samuel W. Fox; The Cheesecake Factory Incorporated.
20191844	G	Antin IV Finco Sarl.; Veolia Environnement S.A.; Antin IV Finco Sarl.
20191845	G	EFR Group Holdings S.a.r.l.; Cumberland Farms, Inc.; EFR Group Holdings S.a.r.l.
20191846	G	salesforce.com, inc.; Optimizer CaymanCo Limited; salesforce.com, inc.
20191852	G	Tenex Capital Partners II, L.P.; Quad-C Partners VIII, L.P.; Tenex Capital Partners II, L.P.
20191853	G	Chemed Corporation; ORIX Corporation; Chemed Corporation.
20191861	G	Cornell Capital Partners LP; Southfield Vanguard Investment LP; Cornell Capital Partners LP.

08/27/2019

20191866	G	TSG8 L.P.; Carousel Capital Partners IV, L.P.; TSG8 L.P.
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08/28/2019

20191851	G	Glaukos Corporation; Avedro, Inc.; Glaukos Corporation.
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08/30/2019

20191644	G	Carlyle Partners VII Cayman, L.P.; Onex Partners III LP; Carlyle Partners VII Cayman, L.P.
20191865	G	Lovell Minnick Equity Partners V LP; InsiderRE Holdings, LLC; Lovell Minnick Equity Partners V LP.
20191875	G	MarketAxess Holdings Inc.; David Rutter; MarketAxess Holdings Inc.
20191876	G	Intact Financial Corporation; Maureen Cowan; Intact Financial Corporation.
20191881	G	Broadcom Inc.; Symantec Corporation; Broadcom Inc.
20191883	G	Wayne Quasha; Steven M. Menzies; Wayne Quasha.
20191884	G	Steven M. Menzies; Berkshire Hathaway, Inc.; Steven M. Menzies.
20191885	G	Axar Special Opportunity Fund V LLC; The J.G. Wentworth Company; Axar Special Opportunity Fund V LLC.
20191890	G	Aflac Incorporated; Nicholas M. Kavouklis; Aflac Incorporated.
20191892	G	Siemens Aktiengesellschaft; Corindus Vascular Robotics, Inc.; Siemens Aktiengesellschaft.
20191898	G	New Mountain Partners V, L.P.; New Mountain Partners V (AIV-C), L.P.; New Mountain Partners V, L.P.

For Further Information Contact: Theresa Kingsberry (202–326–3100), Program Support Specialist, Federal Trade Commission Premerger Notification Office, Bureau of Competition, Room CC–5301, Washington, DC 20024.

By direction of the Commission.

April Tabor,

Acting Secretary.

[FR Doc. 2019–19888 Filed 9–13–19; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0136; Docket No. 2019–0003; Sequence No. 27]

Information Collection; Commercial Item Acquisitions

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, and the Office of Management and Budget (OMB) regulations, DoD, GSA, and NASA invite the public to comment on a revision and renewal concerning commercial item. DoD, GSA, and NASA invite comments on: Whether the proposed collection of information is necessary for the proper performance of the functions of Federal Government acquisitions, including whether the information will have practical utility; the accuracy of the estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. OMB has approved this information collection for use through November 30, 2019. DoD, GSA, and NASA propose that OMB extend its approval for use for three additional years beyond the current expiration date.

DATES: DoD, GSA, and NASA will consider all comments received by November 15, 2019.

ADDRESSES: DoD, GSA, and NASA invite interested persons to submit

comments on this collection by either of the following methods:

- **Federal eRulemaking Portal:** This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the instructions on the site.

- **Mail:** General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405. ATTN: Lois Mandell/IC 9000–0136, Commercial Item Acquisitions.

Instructions: All items submitted must cite Information Collection 9000–0136, Commercial Item Acquisitions. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two-to-three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Michael O. Jackson, Procurement Analyst, at telephone 202–208–4949, or email at michael.o.jackson@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and Any Associated Form(s)

9000–0136, Commercial Item Acquisitions.

B. Needs and Uses

The Federal Acquisition Streamlining Act of 1994 reformed Federal acquisition statutes to encourage and facilitate the acquisition of commercial items and services by the Federal Government. Accordingly, DoD, NASA, and GSA amended the Federal Acquisition Regulation (FAR) to include streamlined/simplified procedures for the acquisition of commercial items.

Pertinent to this information collection, FAR Provision 52.212–3, “Offeror Representations and Certifications—Commercial Items,” was implemented to combine the multitude of individual provisions used in Government solicitations into a single provision for use in commercial acquisitions. The provision is among the representations and certifications that are available for completion in the System for Award Management (SAM).

C. Annual Burden

Respondents: 430,324.

Total Annual Responses: 628,273.

Total Burden Hours: 314,137.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0136, Commercial Item Acquisitions, in all correspondence.

Dated: September 11, 2019.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2019–19939 Filed 9–13–19; 8:45 am]

BILLING CODE 6820–EP–P

GENERAL SERVICES ADMINISTRATION

[Notice–WSSC–2019–04; Docket No. 2019–0004; Sequence No. 4]

Women’s Suffrage Centennial Commission; Notification of Public Meeting

AGENCY: Women’s Suffrage Centennial Commission, General Services Administration.

ACTION: Meeting notice.

SUMMARY: Meeting notice is being provided according to the requirements of the Federal Advisory Committee Act. This notice provides the schedule and agenda for the October 3, 2019, in-person meeting of the Women’s Suffrage Centennial Commission (Commission). The meeting is open to the public.

DATES: The meeting will be held on Thursday, October 3, 2019, beginning at 9:00 a.m., EDT (Eastern Daylight Time), and ending no later than 4:00 p.m., EDT.

ADDRESSES: The meeting will be held at The Workhouse Arts Center, 9518 Workhouse Way, Lorton, VA 22079. The public may also dial into the meeting by calling 1–510–338–9438 Meeting number (access code): 795 610 599

FOR FURTHER INFORMATION CONTACT: Kim Oliver, Designated Federal Officer, Women’s Suffrage Centennial Commission, 1849 C Street NW, Room 7313, Washington, DC 20240; phone: (202) 208–7301; fax: (202) 219–2100; email: kmoliver@blm.gov.

SUPPLEMENTARY INFORMATION:

Background

Congress passed legislation to create the Women’s Suffrage Centennial Commission Act, a bill, “to ensure a suitable observance of the centennial of the passage and ratification of the 19th Amendment of the Constitution of the

United States providing for women's suffrage."

The duties of the Commission, as written in the law, include: (1) To encourage, plan, develop, and execute programs, projects, and activities to commemorate the centennial of the passage and ratification of the 19th Amendment; (2) To encourage private organizations and State and local Governments to organize and participate in activities commemorating the centennial of the passage and ratification of the 19th Amendment; (3) To facilitate and coordinate activities throughout the United States relating to the centennial of the passage and ratification of the 19th Amendment; (4) To serve as a clearinghouse for the collection and dissemination of information about events and plans for the centennial of the passage and ratification of the 19th Amendment; and (5) To develop recommendations for Congress and the President for commemorating the centennial of the passage and ratification of the 19th Amendment.

Meeting Agenda for October 3, 2019

- Call to Order, Opening Remarks, Roll Call
- Housekeeping Announcement
- Approval of Meeting Minutes
- Executive Director Update
- Communications Update
- Subcommittee Updates
- Lunch Break (*Presentation*)
- Public Comment
- Wrap Up/Next Steps
- Adjourn

The meetings are open to the public, but pre-registration is required. Any individual who wishes to attend the meeting should register via email at kmoliver@blm.gov or telephone 202–208–7301.

Interested persons may choose to make a public comment at the meeting during the designated time for this purpose. Public comments shall be limited by minutes based on the number of participants signed up to comment for the allotted time, and subject to agenda time changes based on the speed of the commission's work through the agenda. Speakers who wish to expand upon their oral statements, or those who had wished to speak but could not be accommodated on the agenda, may submit written statements up to 30 days after the meeting.

Members of the public may also choose to submit written comments by mailing them to Kim Oliver, Designated Federal Officer, 1849 C Street NW, Room 7313, Washington, DC 20240, or via email at kmoliver@blm.gov. Please contact Ms. Oliver at the email address

above to obtain meeting materials. All written comments received will be provided to the Commission. Detailed minutes of the meeting will be available for public inspection within 90 days of the meeting.

Individuals requiring special accommodations to access the public meeting should contact Ms. Oliver at least five business days prior to each meeting, so that appropriate arrangements can be made.

Public Disclosure of Comments

Before including your address, phone number, email address, or other personally identifiable information (PII) in your comment, you should be aware that your entire comment—including your PII—may be made publicly available at any time.

While you can ask us in your comment to withhold your PII from public review, we cannot guarantee that we will be able to do so.

Dated: September 5, 2019.

Rebecca Kleefisch,

Executive Director, Women's Suffrage Centennial Commission.

[FR Doc. 2019–19987 Filed 9–13–19; 8:45 am]

BILLING CODE 3420–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Performance Review Board Members

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) located within the Department of Health and Human Services (HHS) is publishing the names of the Performance Review Board Members who are reviewing performance of Senior Executive Service (SES) members, Title 42 (T42) executives, and Senior Level (SL) employees for Fiscal Year 2019.

FOR FURTHER INFORMATION CONTACT:

Sandra De Shields, Team Chief, Executive and Scientific Resources Office, Human Resources Office, Centers for Disease Control and Prevention, 11 Corporate Square Blvd., Mailstop US11–2, Atlanta, Georgia 30341, Telephone (770) 488–0252.

SUPPLEMENTARY INFORMATION: Title 5, U.S.C. Section 4314(c) (4) of the Civil Service Reform Act of 1978, Public Law 95–454, requires that the appointment

of Performance Review Board Members be published in the **Federal Register**.

The following persons will serve on the CDC Performance Review Board, which will oversee the evaluation of performance appraisals of Senior Executive Service members for the Fiscal Year 2019 review period:

Dean, Hazel, Co-Chair
Shelton, Dana, Co-Chair
Arispe, Irma
Boyle, Coleen
Curlee, Robert C.
Kitt, Margaret
Kosmos, Christine
Peeples, Amy
Pirkle, James
Qualters, Judith
Ruiz, Roberto
Smagh, Kalwant

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2019–19957 Filed 9–13–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6063–N5]

Medicare Program; Extension of Prior Authorization for Repetitive Scheduled Non-Emergent Ambulance Transports

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a 1-year extension of the Medicare Prior Authorization Model for Repetitive Scheduled Non-Emergent Ambulance Transport. The extension of this model is applicable to the following states and the District of Columbia: Delaware, Maryland, New Jersey, North Carolina, Pennsylvania, South Carolina, Virginia, and West Virginia.

DATES: This extension begins on December 2, 2019 and ends on December 1, 2020.

FOR FURTHER INFORMATION CONTACT:

Angela Gaston, (410) 786–7409.

Questions regarding the Medicare Prior Authorization Model Extension for Repetitive Scheduled Non-Emergent Ambulance Transport should be sent to AmbulancePA@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Medicare may cover ambulance services, including air ambulance (fixed-wing and rotary-wing) services,

only if the ambulance service is furnished to a beneficiary whose medical condition is such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided in order for the billed service to be considered medically necessary.

Non-emergent transportation by ambulance is appropriate if either the—(1) beneficiary is bed-confined and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or (2) beneficiary's medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required. Thus, bed confinement is not the sole criterion in determining the medical necessity of non-emergent ambulance transportation; rather, it is one factor that is considered in medical necessity determinations.¹

A repetitive ambulance service is defined as medically necessary ambulance transportation that is furnished in 3 or more round trips during a 10-day period, or at least 1 round trip per week for at least 3 weeks.² Repetitive ambulance services are often needed by beneficiaries receiving dialysis or cancer treatment.

Medicare may cover repetitive, scheduled non-emergent transportation by ambulance if the—(1) medical necessity requirements described previously are met; and (2) ambulance provider/supplier, before furnishing the service to the beneficiary, obtains a written order from the beneficiary's attending physician certifying that the medical necessity requirements are met (see 42 CFR 410.40(d)(1) and (2)).³

In addition to the medical necessity requirements, the service must meet all other Medicare coverage and payment requirements, including requirements relating to the origin and destination of the transportation, vehicle and staff, and billing and reporting. Additional information about Medicare coverage of ambulance services can be found in 42 CFR 410.40, 410.41, and in the Medicare Benefit Policy Manual (Pub. 100-02), Chapter 10, at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c10.pdf>.

According to a study published by the Government Accountability Office in October 2012, entitled “Costs and Medicare Margins Varied Widely;

Transports of Beneficiaries Have Increased,”⁴ the number of basic life support (BLS) non-emergent transports for Medicare Fee-For-Service beneficiaries increased by 59 percent from 2004 to 2010. A similar finding published by the Department of Health and Human Services' Office of Inspector General (OIG) in a 2006 study, entitled “Medicare Payments for Ambulance Transports,”⁵ indicated a 20 percent nationwide improper payment rate for non-emergent ambulance transport. Likewise, in June 2013, the Medicare Payment Advisory Commission published a report⁶ that included an analysis of non-emergent ambulance transports to dialysis facilities and found that, during the 5-year period between 2007 and 2011, the volume of transports to and from a dialysis facility increased 20 percent, more than twice the rate of all other ambulance transports combined. More recently, in September 2015, the OIG reported⁷ that approximately one in five ambulance suppliers had questionable billing, and that suppliers that had questionable billing provided nonemergency basic life support transports more often than other suppliers.

Section 1115A of the Social Security Act (the Act) authorizes the Secretary to test innovative payment and service delivery models expected to reduce program expenditures, while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries.

In the November 14, 2014 **Federal Register** (79 FR 68271), we published a notice entitled “Medicare Program; Prior Authorization of Repetitive Scheduled Non-emergent Ambulance Transports,” which announced the implementation of a 3-year Medicare Prior Authorization model under the authority of section 1115A of the Act that established a process for requesting prior authorization for repetitive, scheduled non-emergent ambulance transport rendered by ambulance suppliers garaged in three states (New Jersey, Pennsylvania, and South Carolina). These states were selected as the initial states for the model because of their high utilization and improper

payment rates for these services. The model began on December 1, 2014, and was originally scheduled to end in all three states on December 1, 2017.

In the October 23, 2015 **Federal Register** (80 FR 64418), we published a notice titled “Medicare Program; Expansion of Prior Authorization of Repetitive Scheduled Non-emergent Ambulance Transports,” which announced the inclusion of six additional states (Delaware, the District of Columbia, Maryland, North Carolina, West Virginia, and Virginia) in the Repetitive Scheduled Non-Emergent Ambulance Transport Prior Authorization model in accordance with section 515(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10). These six states began participation on January 1, 2016, and the model was originally scheduled to end in all nine model states on December 1, 2017.

In the December 12, 2017 **Federal Register** (82 FR 58400), we published a notice titled “Medicare Program; Extension of Prior Authorization for Repetitive Scheduled Non-Emergent Ambulance Transports,” which announced a 1-year extension of the prior authorization model in all states through December 1, 2018.

In the December 4, 2018 **Federal Register** (83 FR 62577), we published a notice titled “Medicare Program; Extension of Prior Authorization for Repetitive Scheduled Non-Emergent Ambulance Transports,” which announced a 1-year extension of the prior authorization model in all states through December 1, 2019.

II. Provisions of the Notice

This notice announces that the testing of the model under section 1115A of the Act is again being extended in the current model states of Delaware, the District of Columbia, Maryland, New Jersey, North Carolina, Pennsylvania, South Carolina, Virginia, and West Virginia for an additional year while we continue to work towards nationwide expansion under section 1834(l)(16) of the Act. The existing testing of the model under section 1115A authority is currently scheduled to end in all states on December 1, 2019; however, this notice extends the model under the authority in section 1115A of the Act through December 1, 2020.

Under this extension of the model under section 1115A authority, we will continue to test whether prior authorization helps reduce expenditures, while maintaining or improving quality of care, using the prior authorization process as described in 83 FR 62577. Section 1115A(d)(1) of

¹ 42 CFR 410.40(d)(1).

² Program Memorandum Intermediaries/Carriers, Transmittal AB-03-106.

³ Per 42 CFR 410.40(d)(2), the physician's order must be dated no earlier than 60 days before the date the service is furnished.

⁴ Government Accountability Office “Cost and Medicare Margins Varied Widely; Transports of Beneficiaries Have Increased” (GAO-13-6) (October 2012).

⁵ Office of Inspector General “Medicare Payment for Ambulance Transport” (January 2006).

⁶ Medicare Payment Advisory Commission, June 2013, pages 167–193.

⁷ Office of Inspector General “Inappropriate Payments and Questionable Billing for Medicare Part B Ambulance Transports” (September 2015).

the Act authorizes the Secretary to waive such requirements of Titles XI and XVIII, as well as sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and 1934 (other than subsections (b)(1)(A) and (c)(5)) of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. Consistent with this standard, we will continue to waive the same provisions of Title XVIII for the extension of this model as have been waived for purposes of testing the model over the previous five years. Additionally, we have determined that the implementation of this model does not require the waiver of any fraud and abuse law, including sections 1128A, 1128B, and 1877 of the Act. Thus ambulance suppliers affected by this model must comply with all applicable fraud and abuse laws.

We will continue to use this prior authorization process to help ensure that all relevant clinical or medical documentation requirements are met before services are furnished to beneficiaries and before claims are submitted for payment. The prior authorization process further helps to ensure that payment complies with Medicare documentation, coverage, payment, and coding rules.

The use of prior authorization does not create new clinical documentation requirements. Instead, it requires the same information that is already required to support Medicare payment, just earlier in the process. Prior authorization allows ambulance suppliers to address coverage issues prior to furnishing services.

The prior authorization process under the extension of the model under 1115A authority will continue to apply in the nine states listed previously for the following codes for Medicare payment:

- A0426 Ambulance service, advanced life support, non-emergency transport, Level 1 (ALS1).
- A0428 Ambulance service, BLS, non-emergency transport.

While prior authorization is not needed for the mileage code, A0425, a prior authorization decision for an A0426 or A0428 code will automatically include the associated mileage code.

Under the model extension under section 1115A authority, we will continue our outreach and education efforts to ambulance suppliers, as well as beneficiaries, through such methods as updating the operational guide, frequently asked questions (FAQs) on our website, a physician letter explaining the ambulance suppliers' need for the proper documentation, and

educational events and materials issued by the Medicare Administrative Contractors (MACs).

We will continue to work to limit any adverse impact on beneficiaries and to educate beneficiaries about the model process. If a prior authorization request is non-affirmed, and the claim is still submitted by the ambulance supplier, the claim will be denied, but beneficiaries will continue to have all applicable administrative appeal rights. We will also continue our initiative to help find alternative resources for beneficiaries who do not meet the requirements of the Medicare repetitive scheduled non-emergent ambulance transport benefit.

Additional information is available on the CMS website at <http://go.cms.gov/PAAmbulance>.

III. Collection of Information Requirements

Section 1115A(d)(3) of the Act states that chapter 35 of title 44, United States Code (the Paperwork Reduction Act of 1995), shall not apply to the testing and evaluation of models or expansion of such models under this section. Consequently, this document need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Regulatory Impact Statement

This document announces a 1-year extension of the Medicare Prior Authorization Model for Repetitive Scheduled Non-Emergent Ambulance Transport. Therefore, there are no regulatory impact implications associated with this notice.

Authority: Section 1115A of the Social Security Act.

Dated: August 22, 2019.

Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019-19886 Filed 9-13-19; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-R-153]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by October 16, 2019.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 *OR*, Email: OIRA_submission@omb.eop.gov.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

2. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of

information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection*

Request: Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Use Review (DUR) Program; *Use:* States must provide for a review of drug therapy before each prescription is filled or delivered to a Medicaid patient. This review includes screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Pharmacists must make a reasonable effort to obtain, record, and maintain Medicaid patient profiles. These profiles must reflect at least the patient's name, address, telephone number, date of birth/age, gender, history, *e.g.*, allergies, drug reactions, list of medications, and pharmacist's comments relevant to the individual's drug therapy.

The States must conduct RetroDUR which provides for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, inappropriate or medically unnecessary care. Patterns or trends of drug therapy problems are identified and reviewed to determine the need for intervention activity with pharmacists and/or physicians. States may conduct interventions via telephone, correspondence, or face-to-face contact.

Annual reports are submitted to CMS for the purposes of monitoring compliance and evaluating the progress of States' DUR programs. The information submitted by States is reviewed and results are compiled by CMS in a format intended to provide information, comparisons, and trends related to States' experiences with DUR. States benefit from the information and may enhance their programs each year based on State reported innovative practices that are compiled by CMS from the DUR annual reports. *Form*

Number: CMS–R–153 (OMB control number: 0938–0659); *Frequency:* Yearly, quarterly, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 663; *Total Annual Hours:* 41,004. (For policy questions regarding this collection contact Mike Forman at 410–786–2666.)

Dated: September 11, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–19967 Filed 9–13–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0113]

Facta Farmaceutici S.p.A., et al.; Withdrawal of Approval of 23 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of February 5, 2019. The document announced the withdrawal of approval of 23 abbreviated new drug applications (ANDAs) from multiple applicants, effective March 7, 2019. The document erroneously included ANDA 077895 for Ursodiol Capsules USP, 300 milligrams, held by Impax Laboratories, LLC. This notice corrects that error.

FOR FURTHER INFORMATION CONTACT: Jennifer Forde, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993, 301–348–3035.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of Tuesday, February 5, 2019 (84 FR 1745), in FR Doc. 2019–01129, the following correction is made:

1. On page 1746, in the table, the entry for ANDA 077895 is removed.

In a separate notice published in this issue of the **Federal Register**, FDA is withdrawing the approval of ANDA 077895 under 21 CFR 314.150(d).

Dated: September 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19920 Filed 9–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–P–3347]

Medical Devices; Exemption From Premarket Notification: Class II; Powered Wheeled Stretcher; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it has received a petition requesting exemption from the premarket notification requirements for powered wheeled stretchers. These devices are battery-powered tables with wheels that are intended for medical purposes for use by patients who are unable to propel themselves independently and who must maintain a prone or supine position for prolonged periods because of skin ulcers or contractures (muscle contractions). FDA is publishing this notice to obtain comments in accordance with procedures established by the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments by November 15, 2019.

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 November 15, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 15, 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.

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-P-3347 for "Medical Devices; Exemption From Premarket Notification: Powered Wheeled Stretcher." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The

Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Bryan Benesch, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1538, Silver Spring, MD 20993-0002, 301-796-5506.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

FDA classifies devices into one of three regulatory classes: class I, class II, or class III, based on the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness (see section 513 of the FD&C Act (21 U.S.C. 360c)). Section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and the implementing regulations, 21 CFR part 807 subpart E, require persons who intend to market a new device to submit and obtain clearance of a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is "substantially equivalent" within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

The 21st Century Cures Act (Pub. L. 114-255) (Cures Act) was signed into law on December 13, 2016. Section 3054

of the Cures Act amended section 510(m) of the FD&C Act. As amended, section 510(m)(2) of the FD&C Act provides that, 1 calendar day after the date of publication of the final list under paragraph (1)(B), FDA may exempt a class II device from the requirement to submit a report under section 510(k) of the FD&C Act upon its own initiative or a petition of an interested person, if FDA determines that a report under section 510(k) is not necessary to assure the safety and effectiveness of the device. To do so, FDA must publish in the **Federal Register** notice of its intent to exempt the device, or the petition, and provide a 60-calendar day period for public comment. Within 120 days after the issuance of this notice, FDA must publish an order in the **Federal Register** that sets forth its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the Agency issued on February 19, 1998, entitled "Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff." (Class II 510(k) Exemption Guidance) (available at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf>). As discussed in that guidance document, FDA generally considers the following factors to determine whether a report under section 510(k) is necessary for class II devices: (1) The device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device; (2) characteristics of the device necessary for its safe and effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification. FDA may also consider that, even when exempting devices, these devices would

still be subject to the general limitations on exemptions.

III. Proposed Class II Device Exemptions

FDA has received the following petition requesting an exemption from premarket notification for a class II device: Stryker, 3800 East Centre Ave., Portage, MI 49002, for powered wheeled stretcher, classified under 21 CFR 890.3690. With this notice FDA is seeking comments on the petition in accordance with section 510(m)(2) of the FD&C Act.

IV. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120.

Dated: September 11, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19978 Filed 9–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3839]

Impax Laboratories, LLC; Withdrawal of Approval of an Abbreviated New Drug Application for Ursodiol Capsules USP, 300 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing the approval of abbreviated new drug application (ANDA) 077895 for Ursodiol Capsules USP, 300 milligrams (mg), held by Impax Laboratories, LLC (Impax). Impax requested withdrawal of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of September 16, 2019.

FOR FURTHER INFORMATION CONTACT: Jennifer Forde, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993–0002, 301–348–3035.

SUPPLEMENTARY INFORMATION: On July 27, 2006, FDA approved ANDA 077895 for Ursodiol Capsules USP, 300 mg, submitted by CorePharma, LLC (CorePharma). According to annual reports filed with the Agency, this product has not been commercially manufactured since February 2010.

In a letter dated August 9, 2011, FDA informed CorePharma that it had concerns about the validity of bioequivalence data submitted with ANDA 077895 from studies conducted by a certain contract research organization intended to establish bioequivalence of CorePharma's product to its reference listed drug (RLD), new drug application 019594, Actigall (Ursodiol) Capsules, 300 mg. In that letter, FDA directed CorePharma to supplement its ANDA with either: (1) New bioequivalence studies or (2) re-assays of the samples from the original bioequivalence studies. In a letter dated January 26, 2012, CorePharma submitted a request for an extension of time to submit new bioequivalence data in response to the Agency's August 9, 2011, letter. On February 10, 2012, the Agency granted CorePharma's request for an extension to submit new bioequivalence data by October 30, 2012.

FDA subsequently sent another letter to CorePharma on August 19, 2016, requesting that CorePharma provide the requested bioequivalence data within 30 calendar days or voluntarily seek withdrawal of ANDA 077895 under § 314.150(d) (21 CFR 314.150(d)). In response to the August 19, 2016, correspondence, FDA received a letter from CorePharma dated September 7, 2016, stating that CorePharma did not wish to request the withdrawal of approval of ANDA 077895 for Ursodiol Capsules. In February 2017, the Agency was notified that the ownership of ANDA 077895 was transferred from CorePharma to Impax.

On April 24, 2017, FDA issued a letter to Impax, noting that as of the date of the April 24, 2017, letter, FDA had not received the requested bioequivalence data. In the April 24, 2017, correspondence, FDA strongly suggested to Impax that it voluntarily seek withdrawal of ANDA 077895 under § 314.150(d) as a result of failing to provide data and information establishing bioequivalence to the RLD. In a letter dated February 25, 2019, Impax informed FDA that it would like to request the withdrawal of ANDA 077895 under § 314.150(d). Additionally, in a March 14, 2019,

correspondence to FDA, Impax waived any opportunity for hearing provided under § 314.150(a).

In the **Federal Register** of February 5, 2019 (84 FR 1745), FDA erroneously included ANDA 077895 in a list of drug applications for which approval was being withdrawn under § 314.150(c). Elsewhere in this issue of the **Federal Register** FDA is publishing a correction to that notice to remove ANDA 077895 from the list of applications whose approval was withdrawn under § 314.150(c). In addition, for the reasons discussed above, and because of Impax's request, FDA is withdrawing approval of ANDA 077895, and all amendments and supplements thereto, under § 314.150(d). Distribution of Ursodiol Capsules USP, 300 mg, in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: September 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19908 Filed 9–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3277]

Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection and/or Diagnosis of Zika Virus

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Siemens Healthcare Diagnostics, Inc. (Siemens), for the ADVIA Centaur Zika test. FDA revoked this Authorization on July 17, 2019, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), in consideration of the premarket notification submission submitted to FDA by Siemens for the ADVIA Centaur Zika test that was determined to be substantially equivalent to a legally marketed class II predicate device on July 17, 2019. The revocation, which includes an explanation of the reasons for revocation, is reprinted in this document.

DATES: The Authorization is revoked as of July 17, 2019.

ADDRESSES: Submit written requests for single copies of the revocation to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993-0002, 240-402-8155 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3), as amended by the Project BioShield Act of 2004 (Pub. L. 108-276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of

an unapproved medical product or an unapproved use of an approved medical product in certain situations. On September 18, 2017, FDA issued an EUA to Siemens, for the ADVIA Centaur Zika test, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on November 17, 2017 (82 FR 54361), as required by section 564(h)(1) of the FD&C Act. In response to requests from Siemens, the EUA was amended on November 16, 2017, and April 18, 2019. Subsequently, on May 23, 2019, FDA classified a de novo application for a generic Zika virus serological reagents device as Class II (special controls) under product code QFO (https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180069.pdf). Under section 564(g)(2) of the FD&C Act, the Secretary of Health and Human Services may revoke an EUA if, among other things, the criteria for issuance are no longer met.

II. EUA Criteria for Issuance No Longer Met

On July 17, 2019, FDA revoked the EUA for Siemens' ADVIA Centaur Zika test because the criteria for issuance were no longer met. Under section 564(c)(3) of the FD&C Act, an EUA may be issued only if FDA concludes there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the

disease or condition. FDA has determined that the criteria for issuance of such authorization under section 564(c)(3) of the FD&C Act are no longer met because Siemens' ADVIA Centaur Zika test was determined on July 17, 2019, to be substantially equivalent to a legally marketed class II predicate device with the generic name "Zika virus serological reagents" (https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191578.pdf). As such, FDA concluded that there is an adequate, approved, and available alternative for diagnosing Zika virus infection for purposes of section 564(c)(3) of the FD&C Act and accordingly revoked the Authorization pursuant to section 564(g)(2)(B) of the FD&C Act.

III. Electronic Access

An electronic version of this document and the full text of the revocation are available on the internet at <https://www.regulations.gov/>.

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g) of the FD&C Act are met, FDA has revoked the EUA for Siemens' ADVIA Centaur Zika test. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164-01-P



July 17, 2019

Matthew Gee, M.Sc.
Senior Manager, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591

Dear Mr. Gee:

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA170005) for emergency use of Siemens Healthcare Diagnostics Inc.'s ("Siemens") ADVIA Centaur Zika test, issued on September 18, 2017, and amended on November 16, 2017, and April 18, 2019.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revised or revoked when the criteria under section 564(b)(1) of the Act no longer exist, the criteria under section 564(c) of the Act for issuance of such authorization are no longer met, or other circumstances make such revision or revocation appropriate to protect the public health or safety.

FDA has determined that the criteria for issuance of such authorization under section 564(c) of the Act are no longer met. Under section 564(c)(3) of the Act, an EUA may be issued only if FDA concludes there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition. Siemens submitted a premarket submission to FDA for the ADVIA Centaur Zika test (K191578) that was determined to be substantially equivalent to a legally marketed Class II predicate device, classified under 21 CFR 866.3935, with the generic name "Zika virus serological reagents," on July 17, 2019. FDA has concluded "that this is an adequate, approved¹, and available alternative for diagnosing Zika virus infection for purposes of section 564(c)(3) of the Act."

Accordingly, FDA revokes EUA170005 for emergency use of the ADVIA Centaur Zika test, pursuant to section 564(g)(2) of the Act. As of the date of this letter, the ADVIA Centaur Zika test that was authorized by FDA for emergency use under EUA170005 is no longer authorized by FDA.

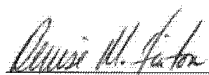
¹ In the context of section 564 of the Act, the term "approved" refers to a product that is approved, licensed, or cleared under section 505, 510(k), or 515 of the Act or section 351 of the Public Health Service Act. See section 564(a)(2) of the Act.

Page 2 – Mr. Gee, Siemens Healthcare Diagnostics Inc.

FDA does not have concerns with the use of any remaining inventory of the ADVIA Centaur Zika test that was distributed prior to revocation of the EUA, when such product is used in conjunction with the ADVIA Centaur Zika test labeling associated with the device cleared on July 17, 2019, under premarket notification submission K191578. FDA encourages the relabeling of any product already manufactured, but not distributed prior to the revocation of the EUA, with the ADVIA Centaur Zika test labeling associated with the device cleared on July 17, 2019, under premarket notification submission K191578. Importantly, the ADVIA Centaur Zika test product for which FDA had issued an EUA and the device cleared under K191578 are manufactured under the same quality system. Siemens should instruct customers who have remaining ADVIA Centaur Zika test EUA product inventory to either use their EUA product in combination with the labeling associated with the device cleared on July 17, 2019, under premarket notification submission K191578, or to work with Siemens to replace the EUA product with the device cleared under K191578. FDA encourages Siemens to use all appropriate means (e.g., mail, email, or website link) to notify affected customers of the EUA revocation and provide access to the labeling associated with the device cleared on July 17, 2019, under premarket notification submission K191578.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,



RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Dated: September 11, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-19982 Filed 9-13-19; 8:45 am]

BILLING CODE 4164-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Minority Health

AGENCY: Office of Minority Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the Advisory Committee on Minority Health (ACMH) will hold a meeting conducted as a telephone conference call. This call will be open to the public. Preregistration is required for both public participation and comment. Any individual who wishes to participate in the call should email OMH-ACMH@hhs.gov by September 25, 2019. Information about the meeting is available from the designated contact person noted below and will be posted on the website for the Office of Minority

Health (OMH):

www.minorityhealth.hhs.gov.

Information about ACMH activities can be found on the OMH website under the heading *About OMH*.

DATES: The conference call will be held on Friday, September 27, 1:00 p.m. to 3:00 p.m. ET.

ADDRESSES: Instructions regarding participating in the conference call will be given at the time of preregistration.

FOR FURTHER INFORMATION CONTACT: Violet Woo, Designated Federal Officer, Advisory Committee on Minority Health, Office of Minority Health, Department of Health and Human Services, Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852. Phone: 240-453-8222; fax: 240-453-8223; email OMH-ACMH@hhs.gov.

SUPPLEMENTARY INFORMATION: In accordance with Public Law 105-392, the ACMH was established to provide advice to the Deputy Assistant Secretary for Minority Health on improving the health of each racial and ethnic minority group and on the development of goals and specific program activities of the OMH.

The topics to be discussed during this meeting will include strategies to address HIV-related health disparities

among racial and ethnic minority populations. The recommendations will be given to the Deputy Assistant Secretary for Minority Health to inform OMH and the Office of Infectious Disease and HIV/AIDS Policy of efforts related to the federal *Ending the HIV Epidemic Initiative*. This call will be limited to 125 participants. Individuals who plan to participate and need special assistance, should contact BLH Technologies, Inc. at (240) 399-8735 and reference this conference call meeting at least five (5) business days prior to the meeting.

Any members of the public who wish to have electronic or printed material distributed to ACMH members should email OMH-ACMH@hhs.gov or mail their materials to the Designated Federal Officer, ACMH, Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852, for receipt prior to close of business on Friday, September 20, 2019.

Dated: September 11, 2019.

Violet Woo,

Designated Federal Officer, Advisory Committee on Minority Health.

[FR Doc. 2019-19933 Filed 9-13-19; 8:45 am]

BILLING CODE 4150-29-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Institute of Mental Health; 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: National Institute of Mental Health Special Emphasis Panel; NIMH Pilot Effectiveness Trials for Treatment, Preventive, and Services Interventions (R34).

Date: October 15, 2019.

Time: 12:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Karen Gavin-Evans, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 6153, MSC, 9606 Bethesda, MD 20892, 301-451-2356, gavinevanskm@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Career Enhancement Award to Advance Autism Services Research.

Date: October 18, 2019.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Aileen Schulte, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC, 9608 Bethesda, MD 20892-9608, 301-443-1225, aschulte@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: September 10, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-19942 Filed 9-13-19; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Cancer 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 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 Cancer Institute Special Emphasis Panel; SBIR Phase IIB Bridge Awards.

Date: October 25, 2019.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove 9609 Medical Center Drive, Room 7W254 Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Eduardo Emilio Chufan, Ph.D., Scientific Review Officer, Research Technology & Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7w254, Bethesda, MD 20892, 240-276-7975, chufanee@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Physical Sciences-Oncology.

Date: November 13, 2019.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NCI Shady Grove, 9609 Medical Center Drive, Room 7W238, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Jeffrey E. DeClue, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, 9609 Medical Center Drive, Room 7W238, National Cancer Institute, NIH, Bethesda, MD 20892-9750, (240) 276-6371, decluej@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Cancer Prevention Clinical Trials Network.

Date: November 15, 2019.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W640, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Saejeong J. Kim, Ph.D., Scientific Review Officer, Special Review

Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W640, Rockville, MD 20850, 240-276-7684, saejeong.kim@nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 10, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-19943 Filed 9-13-19; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Center for Complementary & Integrative Health; 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/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 Center for Complementary and Integrative Health Special Emphasis Panel for Limited Competition: Interdisciplinary Complementary and Integrative Health Clinical Research Training Institutional Research Training Grants (T90/R90) (IT).

Date: October 31, 2019.

Time: 12:00 p.m. to 1:30 p.m.

Agenda: To review and evaluate one grant application.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Martina Schmidt, Ph.D., Chief, Office of Scientific Review, National Center for Complementary & Integrative Health, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, 301-594-3456, schmidma@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: September 10, 2019.
Ronald J. Livingston, Jr.,
Program Analyst, Office of Federal Advisory Committee Policy.
[FR Doc. 2019–19944 Filed 9–13–19; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel, November 8, 2019, 8:30 a.m. to 5:00 p.m., National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20817 which was published in the **Federal Register** on February 11, 2019, 84 FR 3205.

The meeting notice is amended to change the Contact Person from Dr. Richard A. Rippe to Dr. Beata Buzas. Dr. Buzas may be reached at National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6700 B Rockledge Drive, Room 2116, Rockville, MD 20852, 301–443–0800, bbuzas@mail.nih.gov. The meeting is closed to the public.

Dated: September 10, 2019.
Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.
[FR Doc. 2019–19945 Filed 9–13–19; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.
ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained

by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: Technology description follows.

PET Imaging of fungal infections

Available for licensing and commercial development are patent rights covering a PET imaging method for fungal infections, for example, *Aspergillus fumigatus*. Currently, there is a lack of imaging agents specific for fungal infections. L-Rhamnose is selectively uptaken by live *A. fumigatus*. PET imaging experiments showed a 39% increase in uptake by infected mice as opposed to control mice when administered 18F-deoxyrhamnose. As such, the instant imaging agent has potential as a fungal infection diagnostic imaging agent.

Potential Commercial Applications:

- Imaging of live fungal infections
- Imaging of live infections of *A. fumigatus*

Development Stage:

- Preclinical
- Mouse data

Inventors: Dima Hammoud (NIHCC), Rolf Swenson (NHLBI), Xiang (Sean) Zhang (NHLBI), Swati Shah (CC) and Peter Richard Williamson (NIAID).

Intellectual Property: HHS Reference No. E–163–2019–0–US–01 ; U.S Patent Applications 62/882,023 filed August 2, 2019; Klarquist Ref. No. 4239–103017–01.

Licensing Contact: Michael Shmilovich, Esq, CLP; 301–435–5019; shmilovm@mail.nih.gov.

Dated: September 3, 2019.
Michael A. Shmilovich,
Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.
[FR Doc. 2019–19951 Filed 9–13–19; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of AmSpec LLC (Christiansted, St. Croix, USVI) as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of AmSpec LLC (Christiansted, St. Croix, USVI), as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that AmSpec LLC (Christiansted, St. Croix, USVI), has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of June 5, 2019.

DATES: AmSpec LLC (Christiansted, St. Croix, USVI) was approved and accredited as a commercial gauger and laboratory as of June 5, 2019. The next triennial inspection date will be scheduled for June 2022.

FOR FURTHER INFORMATION CONTACT: Dr. Eugene Bondoc, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that AmSpec LLC, 9010 East Cottage, Suite 3, Christiansted, St. Croix, USVI 00820, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. AmSpec LLC (Christiansted, St. Croix, USVI) is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
1	Vocabulary.
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
11	Physical Properties Data.
12	Calculations.
17	Maritime Measurement.

AmSpec LLC (Christiansted, St. Croix, USVI) is accredited for the following laboratory analysis procedures and methods for petroleum and certain

petroleum products set forth by the U.S. American Society for Testing and
Customs and Border Protection Materials (ASTM):
Laboratory Methods (CBPL) and

CBPL No.	ASTM	Title
27-01	D 287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27-02	D 1298	Standard Test Method for Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method.
27-03	D 4006	Standard Test Method for Water in Crude Oil by Distillation.
27-04	D 95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27-05	D 4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27-06	D 473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27-08	D 86	Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure.
27-11	D 445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity).
27-13	D 4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27-14	D 2622	Standard Test Method for Sulfur in Petroleum Products by Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27-48	D 4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
27-50	D 93	Standard Test Methods for Flash-Point by Pensky-Martens Closed Cup Tester.
27-53	D 2709	Standard Test Method for Water and Sediment in Middle Distillate Fuels by Centrifuge.
27-57	D 7039	Standard Test Method for Sulfur in Gasoline and Diesel Fuel by Monochromatic Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27-58	D 5191	Standard Test Method for Vapor Pressure of Petroleum Products (Mini Method).
N/A	D 97	Standard Test Method for Pour Point of Petroleum Products.
N/A	D 130	Standard Test Method for Corrosiveness to Copper from Petroleum Products by Copper Strip Test.
N/A	D 381	Standard Test Method for Gum Content in Fuels by Jet Evaporation.
N/A	D 525	Standard Test Method for Oxidation Stability of Gasoline (Induction Period Method).
N/A	D 1160	Standard Test Method for Distillation of Petroleum Products and Reduced Pressure.
N/A	D 1319	Standard Test Method for Hydrocarbon Types in Liquid Petroleum Products by Fluorescent Indicator Adsorption.
N/A	D 2500	Standard Test Method for Cloud Point of Petroleum Products and Liquid Fuels.
N/A	D 3606	Standard Test Method for Determination of Benzene and Toluene in Finished Motor and Aviation Gasoline by Gas Chromatography.
N/A	D 5769	Determination of Benzene, Toluene, and Total Aromatics in Finished Gasolines by Gas Chromatography/Mass Spectrometry.
N/A	D 7671	Standard Test Method for Corrosiveness to Silver by Automotive Spark-Ignition Engine Fuel-Silver Strip Method.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344-1060. The inquiry may also be sent to CBPGaugersLabs@cbp.dhs.gov. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. <http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories>.

Dated: September 5, 2019.

Dave Fluty,

Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2019-19981 Filed 9-13-19; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-6159-D-01]

Order of Succession for the Office of Housing

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice of Order of Succession.

SUMMARY: In this notice, the Assistant Secretary for Housing—FH Commissioner designates the Order of Succession for the Office of Housing. This Order of Succession supersedes all prior orders of succession for the Assistant Secretary for Housing—FH Commissioner, including the Order of Succession published on April 20, 2015.

DATES: June 20, 2019.

FOR FURTHER INFORMATION CONTACT:

Vance Morris, Acting Associate General Deputy Assistant Secretary, Office of the Assistant Secretary for Housing—Federal Housing Commissioner, Department of Housing and Urban Development, 451 7th Street SW, Room

9100, Washington, DC 20410; telephone number 202-708-2601. (This is not a toll-free number). Persons with hearing or speech impairments may call HUD's toll-free Federal Relay Service at 800-877-8339.

SUPPLEMENTARY INFORMATION: The Assistant Secretary for Housing—FH Commissioner is issuing this Order of Succession of officials authorized to perform the functions and duties of the Assistant Secretary for Housing—FH Commissioner when the Assistant Secretary—FH Commissioner is not available to exercise the powers or perform the duties of the office. This Order of Succession is subject to the provisions of the Federal Vacancies Reform Act of 1998 (5 U.S.C. 3345-3349d).

Today's publication supersedes all prior orders of succession for the Office of Housing, including the Order of Succession notice published on April 20, 2015 (80 FR 21750).

Section A. Order of Succession

Subject to the provisions of the Federal Vacancies Reform Act of 1998,

during any period when, by reason of absence, disability, or vacancy in office, the Assistant Secretary for Housing—FH Commissioner is not available to exercise the powers or perform the duties of the Assistant Secretary for Housing—Federal Housing Commissioner, the following officials within the Office of Housing are hereby designated to exercise the powers and perform the duties of the Office, including the authority to waive regulations. No individual who is serving in an office listed below in an acting capacity may act as the Assistant Secretary for Housing—Federal Housing Commissioner pursuant to this Order of Succession.

- (1) General Deputy Assistant Secretary (GDAS)
- (2) Office of Housing, Chief of Staff
- (3) Associate General Deputy Assistant Secretary (AGDAS)
- (4) Deputy Assistant Secretary for Finance and Budget
- (5) Deputy Assistant Secretary for Operations
- (6) Deputy Assistant Secretary for Multifamily Housing
- (7) Deputy Assistant Secretary for Single Family Housing
- (8) Director, Home Ownership Center (HOC), Philadelphia
- (9) Deputy Assistant Secretary for Risk Management and Regulatory Affairs
- (10) Deputy Assistant Secretary for Healthcare Programs
- (11) Deputy Assistant Secretary for Housing Counseling
- (12) Director, Multifamily Housing, Fort Worth

These officials shall perform the functions and duties of the office in the order specified herein, and no official shall serve unless all other officials whose positions precede his/hers in this order are unable to act by reason of absence, disability, or vacancy in office.

Section B. Authority Superseded

This Order of Succession supersedes all prior orders of succession for the Office of Housing, including the order of succession published on April 20, 2015 at 80 FR 21750.

Authority: Section 7(d), Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: June 20, 2019.

Brian Montgomery,
Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2019–19977 Filed 9–13–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–LE–2019–N099; FF09L00200–FX–LE18110900000; OMB Control Number 1018–0092]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Federal Fish and Wildlife Permit Applications and Reports—Law Enforcement

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service, are proposing to renew an information collection with revisions.

DATES: Interested persons are invited to submit comments on or before October 16, 2019.

ADDRESSES: Send written comments on this information collection request to the Office of Management and Budget's Desk Officer for the Department of the Interior by email at OIRA_Submission@omb.eop.gov; or via facsimile to (202) 395–5806. Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: PRB/PERMA (JAO/1N), 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or by email to Info_Coll@fws.gov. Please reference OMB Control Number 1018–0092 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Madonna L. Baucum, Service Information Collection Clearance Officer, by email at Info_Coll@fws.gov, or by telephone at (703) 358–2503. You may also view the ICR at <http://www.reginfo.gov/public/do/PRAMain>.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

On April 30, 2019, we published a **Federal Register** notice with a 60-day

public comment period soliciting comments on this collection of information (84 FR 18309). In that notice, we solicited comments for 60 days, ending on July 1, 2019. We received one comment which did not address the information collection requirements.

We are again soliciting comments on the information collection request (ICR) that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the Service; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Service enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Service minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Endangered Species Act (ESA; 16 U.S.C. 1531 *et seq.*) makes it unlawful to import or export wildlife or wildlife products for commercial purposes without first obtaining an import/export license (see 16 U.S.C. 1538(d)). The ESA also requires that fish or wildlife be imported into or exported from the United States only at a designated port, or at a nondesignated port under certain limited circumstances (see 16 U.S.C. 1538(f)). This information collection includes the following permit/license application forms:

FWS Form 3–200–2, “Designated Port Exception Permit”

Under 50 CFR 14.11, it is unlawful to import or export wildlife or wildlife products at ports other than those designated in 50 CFR 14.12, unless you qualify for an exception. The following exceptions allow qualified individuals, businesses, or scientific organizations to import or export wildlife or wildlife products at a nondesignated port:

(a) To export the wildlife or wildlife products for scientific purposes;

(b) To minimize deterioration or loss; or

(c) To relieve economic hardship.

To request authorization to import or export of wildlife or wildlife products at nondesignated ports, applicants must complete FWS Form 3–200–2.

Designated port exception permits can be valid for up to 2 years. We may require a permittee to file a report on activities conducted under authority of the permit.

FWS Form 3–200–3a, “Federal Fish and Wildlife Permit Application Form: Import/Export License—U.S. Entities,” and 3–200–3b, “Federal Fish and Wildlife Permit Application Form: Import/Export License—Foreign Entities”

It is unlawful to import or export wildlife or wildlife products for commercial purposes without first obtaining an import/export license (50 CFR 14.91). Applicants located in the United States must complete FWS Form 3–200–3a to request this license. Foreign applicants that reside or are located outside the United States must complete FWS Form 3–200–3b to request this license.

We use the information collected on FWS Forms 3–200–3a/3b as an enforcement tool and management aid to (a) monitor the international wildlife market and (b) detect trends and changes in the commercial trade of wildlife and wildlife products. Import/export licenses are valid for up to 1 year. We may require a licensee to file a report on activities conducted under authority of the import/export license.

Recordkeeping Requirements

Permittees and licensees must maintain records that accurately describe each importation or exportation of wildlife or wildlife products made under the license, and any additional sale or transfer of the wildlife or wildlife products. In addition, licensees must make these records and the corresponding inventory of wildlife or wildlife products available for our inspection at reasonable times, subject to applicable

limitations of law. We believe the burden associated with these recordkeeping requirements is minimal because the records already exist. Importers and exporters must complete FWS Form 3–177 (Declaration for Importation or Exportation of Fish or Wildlife) for all imports or exports of wildlife or wildlife products. This form provides an accurate description of the imports and exports. OMB has approved the information collection for FWS Form 3–177 and assigned OMB Control Number 1018–0012. Normal business practices should produce records (e.g., invoices or bills of sale) needed to document subsequent sales or transfers of the wildlife or wildlife products.

Proposed Revision

With this submission, we propose a revision to the previously approved collection of information. The Service will request OMB approval to transfer the below-listed forms currently approved under OMB Control No. 1018–0093, “Federal Fish and Wildlife Permit Applications and Reports—Management Authority; 50 CFR 12, 13, 14, 15, 16, 17, 18, 21, 23,” into this information collection (OMB Control No. 1018–0092):

- FWS Form 3–200–44, “Permit Application Form: Registration of an Agent/Tannery under the Marine Mammal Protection Act (MMPA),” and
- FWS Form 3–200–44a, “Registered Agent/Tannery Bi-Annual Inventory Report.”

The Service’s Alaska region manages marine mammals that inhabit Alaskan waters, as well as the Alaska Native hunters and handicrafters. Both the registration of an Agent/Tannery form and the Registered Agent/Tannery bi-annual inventory report form are issued and reviewed by the Office of Law Enforcement in the Alaska Region. As such, it is more appropriate that these forms be transferred to, and approved by OMB, under OMB Control No. 1018–0092, “Federal Fish and Wildlife Applications and Reports—Law Enforcement; 50 CFR 13 and 14.”

We use the information collected on FWS Form 3–200–44 for only the

registration of qualified agents and tanneries for polar bear (*Ursus maritimus*), walrus (*Odobenus rosmarus*), and Alaskan sea otter (*Enhydra lutris kenyoni*) under the Marine Mammal Protection Act. This registration facilitates the transfer of marine mammal specimens taken by Alaskan Natives for the purposes of subsistence or creation of authentic Native handicraft articles and clothing.

Biannually (twice a year) on or before the 10th day of January and July, we require that the permittee submit to the Service FWS Form 3–200–44a, containing detailed activities of each registered agent or registered tannery for each transaction related to Polar bear, Walrus, and Alaskan sea otter. If no transactions occurred, the permittee must submit a negative report.

The associated estimated annual burden of Forms 3–200–44/44a is 45 responses and 42 burden hours. If OMB approves this revision request, we will initiate a revision to OMB Control No. 1018–0093 to remove those two forms to avoid duplication of burden.

Title of Collection: Federal Fish and Wildlife Applications and Reports—Law Enforcement; 50 CFR 13 and 14.

OMB Control Number: 1018–0092.

Form Number: FWS Forms 3–200–2, 3–200–3, 3–200–3a, 3–200–44, and 3–200–44a.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: Individuals, private sector, and State/local/Tribal entities.

Respondent’s Obligation: Required to obtain or retain a benefit.

Frequency of Collection: One time for applications, an average of once every 9 days per respondent for fulfillment reports, and biannually (January and July) for agents/tanneries.

Total Estimated Annual Nonhour Burden Cost: \$1,188,100. There is a \$100 fee associated with applications (Forms 3–200–2 and 3–200–3) received from individuals and private sector. There is no fee for applications from government agencies or for processing reports.

Activity/requirement	Estimated number of annual respondents	Estimated number of annual responses	Completion time per response (hours)	Estimated total annual burden hours *
FWS Form 3–200–2, “Designated Port Exception Permit” (50 CFR 13 and 14):				
Individuals	577	577	1.25	721
Private Sector	722	722	1.25	903
Government	13	13	1.25	16
Designated Port Exception Permit Report/Recordkeeping (50 CFR 13 and 14):				
Private Sector	5	5	1	5

Activity/requirement	Estimated number of annual respondents	Estimated number of annual responses	Completion time per response (hours)	Estimated total annual burden hours *
Import/Export License Report/Recordkeeping (50 CFR 13 and 14): Private Sector	10	10	1	10
FWS Form 3–200–3a, “Federal Fish and Wildlife Permit Application Form: Import/Export License—U.S. Entities” (50 CFR 13 and 14): Private Sector	10,197	10,197	1.25	12,746
FWS Form 3–200–3b, “Federal Fish and Wildlife Permit Application Form: Import/Export License—Foreign Entities” (50 CFR 13 and 14): Private Sector	380	380	1.25	475
FWS Forms 3–200–44, “Permit Application Form: Registration of an Agent/Tannery under the Marine Mammal Protection Act (MMPA)”: Private Sector	5	5	.3	2
FWS Form 3–200–44a, “Registered Agent/Tannery Bi-Annual Inventory Report”: Private Sector	20	40	1	40
Total:	11,929	11,949		14,918

* Rounded.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: September 10, 2019.

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2019–19911 Filed 9–13–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190 A2100DD/AAK001030/
A0A501010.999900]

Shawnee Tribe Liquor and Beer Act

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice publishes the liquor control act of the Shawnee Tribe. The Shawnee Tribe Liquor and Beer Act (Act) regulates and controls the possession, sale, manufacture, and distribution of alcohol in conformity with the laws of the State of Oklahoma for the purpose of generating new Tribal revenues. Enactment of this Act will help provide a source of revenue to strengthen Tribal government, provide for the economic viability of Tribal enterprises, and improve delivery of Tribal government services.

DATES: This Act takes effect on September 16, 2019.

FOR FURTHER INFORMATION CONTACT: Ms. Diane Jobe, Tribal Government Services

Officer, Eastern Oklahoma Regional Office, Bureau of Indian Affairs, 3100 West Peak Boulevard, Muskogee, Oklahoma 74402, Telephone: (918) 781–4685, Fax: (918) 781–4649.

SUPPLEMENTARY INFORMATION: Pursuant to the Act of August 15, 1953, Public Law 83–277, 67 Stat. 586, 18 U.S.C. 1161, as interpreted by the Supreme Court in *Rice v. Rehner*, 463 U.S. 713 (1983), the Secretary of the Interior shall certify and publish in the **Federal Register** notice of adopted liquor ordinances for the purpose of regulating liquor transactions in Indian country. The Shawnee Tribe Business Council duly adopted the Shawnee Tribe Liquor and Beer Act on August 9, 2019.

This notice is published in accordance with the authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs. I certify that the Shawnee Tribe Business Council duly adopted by Resolution the Shawnee Tribe Liquor and Beer Act by Resolution No. R–08–09–19–B dated August 9, 2019.

Dated: September 9, 2019.

Tara Sweeney,

Assistant Secretary—Indian Affairs.

SECTION ONE. ENACTMENT. This shall be codified in the Shawnee Tribe Tax Code.

Section 7–101. Findings. The Business Council finds that:

A. It is the policy of the Tribe to raise revenues through the collection of taxes for the sale and distribution of liquor and beer products within Shawnee Indian Country.

B. The Tribe has a duty to provide for the health, safety, and welfare of its citizens.

C. As part of the Tribe’s responsibility to its citizens, the Tribe must regulate

and control the distribution, sale, and possession of alcoholic beverages on tribal lands located within Shawnee Indian Country.

D. Except as otherwise required by other applicable laws of the Shawnee Tribe or by any applicable Federal and State law, the provisions and requirements of this Chapter and any rules, regulations and licenses authorized hereunder shall apply to the sale and distribution of liquor and beer products on properties under the jurisdiction of the Tribe.

Section 7–102. Purpose. The purpose of this Act is to regulate the sale and distribution of liquor and beer products on properties under the jurisdiction of the Shawnee Tribe and to generate an additional revenue base.

Section 7–103. Short Title and Codification. This Act shall be known and may be cited as the Shawnee Tribe Liquor and Beer Act and shall be codified as Chapter Seven of “Revenue and Taxation,” of the Shawnee Tribe.

Section 7–104. Authority. This Act is enacted pursuant to Articles IV, VI and VII, of the Constitution of the Shawnee Tribe and the Congressional Act of August 15, 1953 (Pub. L. 83–277, 67 Stat. 586, 18 U.S.C. 1161).

Section 7–105. Definitions. For purposes of this Chapter, the following words and phrases shall have the meanings respectively ascribed to them in this Section, except where the context otherwise requires:

A. “Alcohol” means a substance known as ethyl alcohol, hydrated oxide of ethyl, or spirit of wine, which is produced by the fermentation or distillation of grain, starch, molasses, sugar, or other substances including all dilutions and mixtures of this substance.

B. "Beer" means any beverage of alcohol by volume and obtained by the alcoholic fermentation of an infusion or decoction of barley, or other grain, malt or similar products. "Beer" may or may not contain hops or other vegetable products. "Beer" includes, among other things, beer, ale, stout, lager beer, porter and other malt or brewed liquors, but does not include sake, known as Japanese rice wine.

C. "Beer Outlet" means retail sale business licensed by the Shawnee Tribe selling beer within the Shawnee Indian Country, including all related and associated facilities under the control of the Operator. Moreover, where an Operator's business is carried on as part of the operation of an entertainment or recreational facility, the "Beer Outlet" shall be deemed to include the entertainment or recreational facility and its associated areas.

D. "Commission" means the Tax Commission of the Shawnee Tribe.

E. "Liquor" means the four varieties of liquor commonly referred to as alcohol, spirits, wine and beer, and all fermented, spirituous, vinous or malt liquors or any other intoxicating liquid, solid, semi-solid or other substance patented or not, containing alcohol, spirits, wine or beer, and is intended for oral consumption.

F. "Liquor Outlet" means retail sale business licensed by the Shawnee Tribe selling liquor within the Shawnee Indian Country, including all related and associated facilities under the control of the Operator. Moreover, where an Operator's business is carried on as part of the operation of an entertainment or recreational facility, the "Liquor Outlet" shall be deemed to include the entertainment or recreational facility and its associated areas.

G. "Tribe" means the Shawnee Tribe as established under the Constitution of the Shawnee Tribe, and any agency, corporation, partnerships, component, or subdivisions of the Shawnee Tribe.

H. "Business Council" means the Shawnee Tribe Business Council as constituted by Article IV of the Constitution of the Shawnee Tribe.

I. "Operator" means a person twenty-one (21) years of age or older who is properly licensed by the Commission to operate a Liquor and/or Beer Outlet.

J. "Person" shall have the meaning defined in Chapter One, Section 1-03 of this Title.

K. "Sale" means any transfer, exchange, or barter, in any manner or by any means whatsoever, for a consideration and includes and means all sales made by any person, whether as principal, proprietor or as an agent,

servant, or employee, association, partnership, or corporation of liquor or beer products.

L. "Wholesaler" means and includes any person doing any such acts or carrying on any such business or businesses that would require such person to obtain a Wholesaler's License or Licenses hereunder.

M. "Wholesale price" means the established price for which liquor or beer are sold to the Shawnee Tribe or any Operator by the manufacturer or distributor or other reduction.

Section 7-106. *Severability*. In the event that any provision or provisions of this Act are determined by a court of competent jurisdiction to be invalid for any reason, the remaining provisions of the Act shall be deemed severable from the provision or provisions determined to be invalid and shall remain in full force and effect as though the invalid provisions had never been part of the Act.

Subchapter 2. Prohibition and Conformity With the Laws of the State of Oklahoma

Section 7-201. *General Prohibition*. It shall be unlawful to buy, sell, give away, consume, furnish, or possess any liquor or beer product containing alcohol for ingestion by human beings or to appear or be found in a place where liquor or beer products are sold and/or consumed, except as allowed for under this Act and the regulations promulgated hereunder.

Section 7-202. *Possession for Personal Use*. Possession of liquor or beer products for personal use by persons over the age of twenty-one (21) years shall, unless otherwise prohibited by Federal, State or Shawnee Tribe Law or Regulation, be lawful within the Shawnee Indian Country, so long as said liquor or beer product was lawfully purchased from an establishment duly licensed to sell said beverages, whether on or off the Shawnee Indian Country and consumed within a private residence or at a location or facility licensed for the public consumption of liquor or beer.

Section 7-203. *Conformity with the Laws of the State of Oklahoma*. Federal law prohibits the introduction, possession and sale of liquor in Indian Country (18 U.S.C. 1154 and other statutes), except when the same is in conformity both with laws of the State of Oklahoma and the Tribe (18 U.S.C. 1161). As such, compliance with this Act shall be in addition to and not a substitute for compliance with the laws of the State of Oklahoma. Operators acting pursuant to this Act shall comply with the State of Oklahoma's liquor and

beer laws to the extent required by 18 U.S.C. 1161. However, the Tribe shall have the fullest jurisdiction allowed under the Federal laws over the sale of liquor and beer products, and related products or activities within Shawnee Indian Country.

Subchapter 3. Licensing

Section 7-301. *Licensing of Liquor and Beer Outlets*. The Commission is empowered to do the following duties:

A. Administer this Act by exercising general control, management and supervision of all liquor and beer sales, places of sales and sale outlets, as well as exercising all powers necessary to accomplish the purposes of this Act; and,

B. Adopt and enforce rules and regulations in furtherance of the purposes of this Act and in the performance of its administrative functions.

Section 7-302. *Business Council Approval of Liquor and/or Beer Outlet Locations*.

A. Business Council Approval of Location. The Business Council shall approve all Liquor and/or Beer Outlet locations on Shawnee Indian Country by way of Tribal Resolution prior to the Commission issuing Licenses to said outlet locations.

B. Business Council Location Review. The Business Council may refuse to approve a Liquor and/or Beer Outlet location on the Shawnee Indian Country, pursuant to Section 7-302 of this Act, if the Business Council has reasonable cause to believe that:

1. The proximity of the Liquor and/or Beer Outlet has a detrimental effect upon a religious, cultural, social or governmental institution established or recognized by the Shawnee Tribe; or
2. The Liquor and/or Beer Outlet is within 100 feet of a residential area; or
3. The Business Council determines it is not in the best interest of the Tribe's health, safety or welfare; or
4. There is any other reason as provided for and by Shawnee Tribe law, custom or regulation.

Section 7-303. *Application for Liquor and/or Beer Outlet Licenses*.

A. Application. Any person twenty-one (21) years of age or older may apply to the Commission for a Liquor and/or Beer Outlet License.

B. Licensing Requirements. The person applying for said License must make a showing once a year and must satisfy the Commission that:

1. He/she is a person of good moral character;
2. He/she has never been convicted of violating any laws prohibiting the traffic in any spirituous, vinous, fermented or

malt liquors, or of the gaming laws of the Tribe, State of Oklahoma, any other Tribe or any State of the United States;

3. He/she has never violated the laws commonly called the "Prohibition laws," as defined hereunder or under any subsequent regulations; and,

4. He/she has not had any permit or License to sell alcohol, beer or liquor as provided for in § 7-105 hereof revoked by any governmental authority within the previous one (1) year.

C. *Processing Application.* The Commission shall receive and process applications and be the official representative of the Tribe in all matters related to the receipt of applications, liquor and beer excise tax collections and any other related matters. If the Commission or its authorized representative is satisfied that the applicant is suitable and a responsible person, the Commission or his/her authorized representative may issue a License for the sale of liquor and/or beer products.

D. *Application Fee.* Each application shall be accompanied by an application fee to be set by regulations of the Commission.

E. *Discretionary Licensing.* Nothing herein shall be deemed to create a duty or requirement to issue a License. Issuance of a License is discretionary based upon the Commission's determination of the best interests of the Tribe. A License is a privilege, and not a property right, to sell liquor and/or beer products within the jurisdiction of the Shawnee Tribe at licensed locations, but not operate to confer on, vest in, or license any title, interest or estate in Shawnee Tribe real property.

F. *Temporary or Emergency Licensing.* An applicant for a Liquor and/or Beer Outlet License may apply for a ninety (90) day temporary or emergency License upon showing of good cause for such issuance pending determination upon the regular License application. Such applicant must show they have a valid similar license from another licensing jurisdiction and meet such other written conditions of the Commission as to ensure the health and safety of the public.

Section 7-304. *Liquor and/or Beer Outlet Licenses.* Upon approval of an application, the Commission shall issue the applicant a liquor and/or beer License ("License") which shall be valid for one (1) year from the date of issuance. The License shall entitle the Operator to establish and maintain only the type of outlet permitted on the License. This License shall not be transferable. The Operator must properly and publicly display the License in its place of business. The

License shall be renewable at the discretion of the Commission; provided that the Operator submits an application form and application fee as provided for in Section 7-303. D. of this Act. Provided, a temporary or emergency License shall be valid for not more than ninety (90) days and may not be extended.

Section 7-305. *Other Business by Operator.* An Operator may conduct another business simultaneously with managing a Liquor and/or Beer Outlet; provided if such other business is in any manner affiliated or related to the Liquor and/or Beer Outlet and is not regulated by another entity of the Tribe it must be approved by the Commission prior to the initiation. Said other business may be conducted on same premise as a Liquor and/or Beer Outlet, but the Operator shall be required to maintain separate account books for the other business.

Section 7-306. *Revocation of Operator's License.*

A. Failure of an Operator to abide by the requirements of this Act and any additional regulations or requirements imposed by the Commission shall constitute grounds for revocation of the Operator's License as well as enforcement of the penalties provided for in Section 7-701 of this Act.

B. Upon determining that any person licensed by the Tribe to sell liquor and/or beer is for any reason no longer qualified to hold such License or reasonably appears to have violated any terms of this License or Shawnee Tribe regulations, including failure to pay taxes when due and owing, or have been found by any forum of competent jurisdiction, including the Commission, to have violated the terms of the Tribe's or the State of Oklahoma's license or of any provision of this Act, the Commission shall immediately serve written notice upon the Operator that he/she must show cause within ten (10) calendar days as to why his/her License should not be revoked or restricted. The notice shall state the grounds relied upon for the proposed revocation or restriction. *Provided*, the Commission may immediately, without notice, temporarily revoke or restrict a License if the Commission reasonably believes the public health, safety or welfare is threatened.

C. If the Operator fails to respond to the notice within ten (10) calendar days of service, the Commission may issue an Order revoking the License as the Commission deems appropriate, effective immediately. The Operator may within the ten (10) calendar day period file with the Commission a

written response and request for hearing before the Commission.

D. At the hearing, the Operator may present evidence and argument directed at the issue of whether or not the asserted grounds for the proposed revocation or restriction are in fact true, and whether such grounds justify the revocation or modifications of the License. The Tribe may present evidence as it deems appropriate.

E. The Commission, after considering all of the evidence and arguments, shall issue a written decision either upholding the License, revoking the License or imposing some lesser penalty (such as temporary suspension or fine), and such decision shall be final and conclusive with regard to the Commission. The Commission's fine may be in an amount not to exceed Five-Thousand Dollars (\$5,000) per incident and/or violation. *Provided*, each day of continuing violation after notice to cease by the Commission may be considered a separate violation.

F. The Commission's final decision may be appealed by the Operator to the Shawnee Tribal Court, or appropriate CFR Court, upon posting a bond with the Court Clerk in the amount of the Commission's final hearing assessment or ruling, in compliance with such rules and procedure as generally applicable to court proceedings. *Provided*, any findings of fact of the Commission are conclusive upon the Court unless clearly contrary to law. The purposes of the Court review are not to substitute the Court's finding of facts or opinion for the Commission's, but to guarantee due process of law. If the Court should rule for the appealing party, the Court may sustain, reverse or order a new hearing giving such guidance for the conduct of such as it deems necessary for a fair hearing. No damages or monies may be awarded against the Commission, the Commission or its staff, nor the Tribe, and its agents, officers and employees in such an action.

Section 7-307. *Discretionary Review.* The Commission may refuse to grant a License for the sale of liquor and/or beer products, if the Commission has reasonable cause to believe that the License required by this Act has been obtained by fraud or misrepresentation. The Commission upon proof that said License was so obtained shall upon hearing revoke the same, and all funds paid therefore shall be forfeited.

Subchapter 4. Liquor and Beer Sales and Transportation

Section 7-401. *Sales by Liquor and Beer Wholesalers and Transport of*

Liquor and Beer Upon Shawnee Indian Country.

A. Right of Commission to Scrutinize Suppliers. The Operator of any licensed outlet shall keep the Commission informed, in writing, of the identity of the suppliers and/or Wholesalers who supply or are expected to supply liquor and/or beer products to the outlet(s). The Commission may, at its discretion, limit or prohibit the purchase of said products from a supplier or Wholesaler for the following reasons: Non-payment of Shawnee Tribe taxes, bad business practices, or sale of unhealthy supplies. A ten (10) calendar day notice of stopping purchases ("Stop Purchase Order") shall be given by the Commission whenever purchases from a supplier or Wholesaler are to be discontinued unless there is a health emergency, in which case the Stop Purchase Order may take effect immediately.

B. Freedom of Information from Suppliers/Wholesalers. Operators shall in their purchase of stock and in their business relations with suppliers and Wholesalers cooperate with and assist in the free flow of information and data to the Commission from suppliers and Wholesalers relating to the sales and business arrangements between suppliers and Operators. The Commission may, at his/her discretion, require the receipts from the suppliers of all invoices, bills of lading, billings or documentary receipts of sales to the Operators. All records shall be kept according to Section 7-402. G. of this Act.

Section 7-402. Sales by Retail Operators; Wholesalers/Operators Records.

A. Commission Regulations. The Commission shall adopt regulations that shall supplement this Act and facilitate their enforcement. These regulations shall include prohibitions on sales to minors, where liquor and/or beer may be consumed, persons not allowed to purchase liquor and/or beer, hours and days when outlets may be open for business and any other appropriate matters and controls.

B. Sales to Minors. No person shall give, sell or otherwise supply any liquor and/or beer to any person under the age of twenty-one (21) years of age either for his or her own use or for the use of any other person.

C. Consumption of Liquor and/or Beer upon Licensed Premises. No Operator shall permit any person to open or consume liquor and/or beer on his/her premises and in his/her control unless the Commission allows the consumption of liquor and/or beer and identifies where liquor and/or beer may

be consumed on Shawnee Indian Country.

D. Conduct on Licensed Premises.

1. No Operator shall be disorderly, boisterous or intoxicated on the licensed premises or any public premises adjacent thereto which are under his/her control, nor shall he/she permit disorderly, boisterous or intoxicated person to be thereon; nor shall he/she use or allow the use of profane or vulgar language thereon.

2. No Operator shall permit suggestive, lewd or obscene conduct or acts on his/her premises. For the purpose of this Section, suggestive, lewd or obscene conduct or acts shall be those conduct or acts identified as such by Federal, State of Oklahoma and/or the laws of the Tribe.

E. Employment of Minors. No person under the age of twenty-one (21) years of age shall be employed in any service in connection with the sale or handling of liquor or beer, either on a paid or voluntary basis.

F. Operator's Premises Open to Commission Inspection. The premises of all Operators, including vehicles used in connection with liquor and/or beer sales, shall be open during business hours and at all reasonable times to inspection by the Commission.

G. Wholesaler's/Operator's Records. The originals or copies of all sales slips, invoices and other memoranda covering all purchases of liquor and/or beer by the Operator or Wholesaler shall be kept on file in the retail premises of the Operator or Wholesaler purchasing the sales at least five (5) years after each purchase and shall be filed separately and kept apart from all other records, and as nearly as possible, shall be filed in consecutive order and each month's records kept separate so as to render the same readily available for inspection and checking. All cancelled checks, bank statements, and books of accounting, covering and involving the purchase of liquor and/or beer and all memoranda, if any, showing payment of money for liquor and/or beer other than by check shall be likewise preserved for availability for inspection and checking.

H. Records Confidential. All records of the Commission showing the purchase of liquor and/or beer by any individual or group shall be confidential and shall not be inspected except by the Commission or the Commission's representative, or the Tribe's Attorney or Attorney General, or upon order of the Shawnee Tribal Court, or appropriate CFR Court.

Section 7-403. Transportation Through Shawnee Indian Country Not Affected. Nothing herein shall pertain to the otherwise lawful transportation of

liquor and/or beer through the Shawnee Indian Country by persons remaining upon public roads and highways and where such beverages are not delivered, sold or offered for sale to anyone within the Shawnee Indian Country.

Subchapter 5. Taxation and Audits*Section 7-501. Excise Tax Imposed Upon Distribution of Liquor and/or Beer and Use of Such Tax.*

A. *General Taxation Authority.* The Commission shall have the authority to assess and collect tax on the sale of liquor and/or beer products to the purchaser or consumer. This tax shall be collected and paid to the Commission upon all liquor and/or beer products sold within the jurisdiction of the Tribe. The Business Council shall establish such a rate by resolution and may establish differing rates for any given class of merchandise, which shall be paid prior to the time of retail sale and delivery thereof.

B. *Added to Retail Price.* An excise tax to be set by the Business Council on the wholesale price shall be added to the retail selling price of liquor and/or beer products to be sold to the ultimate consumer or purchaser. All taxes paid pursuant to this Act shall be conclusively presumed to be direct taxes on the retail consumer pre-collected for the purpose of convenience and facility.

C. *Tax Stamp.* Within seventy-two (72) hours after receipt of any liquor and/or beer products by any Wholesaler or retailer subject to this Act, a Shawnee Tribe tax stamp shall be securely affixed thereto denoting the Shawnee Tribe tax thereon. Retailers or sellers of liquor and/or beer products within the Tribe's jurisdiction may buy and sell or have in their possession only liquor and/or beer products which have the Shawnee Tribe tax stamp affixed to each package.

D. *Use of Tax Revenue.* The excise tax imposed and levied hereunder shall be earmarked for expenditures as specified in Chapter One of this Title.

Section 7-502. Audits and Inspections.

A. *Inspections.* All of the books and other business records of the Liquor and/or Beer Outlet shall be available for inspection and audit by the Commission or its authorized representative during normal business hours and at all other reasonable times, as may be requested by the Commission.

B. *Bond for Excise Tax.* The excise tax together with reports on forms to be supplied by the Commission shall be remitted to the Commission on a monthly basis unless otherwise specified in writing by the Commission. The Operator shall furnish a satisfactory

bond to the Commission in an amount to be specified by the Commission guaranteeing his or her payment of excise taxes.

Subchapter 6. Liability, Insurance and Sovereign Immunity

Section 7–601. *Liability for Bills.* The Shawnee Tribe and the Commission shall have no legal responsibility for any unpaid bills owed by a Liquor and/or Beer Outlet to a Wholesaler, supplier, or any other person.

Section 7–602. *Shawnee Tribe Liability and Credit.*

A. *Liability.* Unless explicitly authorized by Shawnee Tribe statute or regulation, Operators are forbidden to represent or give the impression to any supplier or person with whom he or she does business that he or she is an official representative of the Tribe, Commissioner or the Commission authorized to pledge Shawnee Tribe credit or financial responsibility for any of the expenses of his or her business operation. The Operator shall hold the Tribe harmless from all claims and liability of whatever nature. The Commission shall revoke an Operator's outlet License(s) if said outlet(s) is not operated in a businesslike manner or if it does not remain financially solvent or does not pay its operating expenses and bills before they become delinquent.

B. *Insurance.* The Operator shall maintain at his or her own expense adequate insurance covering liability, fire, theft, vandalism and other insurable risks. The Commission may establish as a condition of any License, the required insurance limits and any additional coverage deemed advisable, proof of which shall be filed with the Commission.

Section 7–603. *Sovereign Immunity.* Nothing in this Act shall be construed as a waiver or a limitation of the sovereign immunity of the Shawnee Tribe or its agencies, nor their officers or employees. To the fullest extent possible, the Shawnee Tribe expressly retains its sovereign immunity for the purposes of enactment of this Act.

Subchapter 7. Enforcement

Section 7–701. *Violations and Penalties.* Any person who violates this Act or elicits, encourages, directs, or causes to be violated this Act, or Acts in support of this Act, or regulations of the Commission shall be guilty of an offense and subject to fine. Failure to have a current, valid or proper License shall not constitute a defense to an alleged violation of the licensing laws and/or regulations.

A. *Criminal Penalties.* Any Indian person convicted of committing any

violation of this Act shall be subject to punishment of up to one (1) year imprisonment and/or a fine not to exceed Five Thousand Dollars (\$5,000). The judicial system of the Shawnee Tribe shall have jurisdiction over said proceeding(s).

B. *Civil Liability.* Additionally, any person upon committing any violation of any provision of this Act may be subject to civil action for trespass and upon having been determined by the Shawnee Tribal Court, or appropriate CFR Court, to have committed said violation, shall be found to have trespassed upon the lands of the Tribe and shall be assessed such damages as the Court deems appropriate in the circumstances. The Court also has jurisdiction to enforce any fine, penalty, suspension, revocation or other enforcement action of the Commission. Any Commission action that was not timely appealed is conclusively deemed valid.

C. Any person suspected or having violated any provision of this Act shall, in addition to any other penalty imposed hereunder, be required to surrender any liquor and/or beer products in the person's possession to the officer making the complaint. The surrendered beverages, if previously unopened, shall only be returned upon a finding by the Shawnee Tribal Court, or appropriate CFR Court, after trial or proper judicial proceeding, that the individual committed no violation of this Act.

D. Any Operator who violates the provisions set forth herein shall forfeit all of the remaining stock in the outlet(s). The Commission shall be empowered to seize forfeited products.

E. Any stock, goods or other items subject to this Act that have not been registered, licensed or taxes paid shall be contraband and subject to immediate confiscation by the Commission or his/her employees or agents; provided that within fifteen (15) calendar days of the seizure the Commission shall cause to be filed an action against such property alleging the reason for the seizure or confiscation and upon proof, the Shawnee Tribal Court, or appropriate CFR Court, shall order the property forfeited and vested with the Tribe.

SECTION TWO. EFFECTIVE DATE. This Act shall become effective on the date upon which, after having been certified by the Secretary of the Interior, it is published in the **Federal Register**.

[FR Doc. 2019–20116 Filed 9–12–19; 4:15 pm]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLOR93000 L61400000.HN0000
LXLAH9990000 19X]

Renewal of Approved Information Collection; OMB Control No. 1004–0168

AGENCY: Bureau of Land Management, Interior.

ACTION: 60-Day notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Land Management (BLM) is proposing to renew an information collection with revisions.

DATES: Please submit comments on the proposed information collection by November 15, 2019.

ADDRESSES: Comments may be submitted by mail, fax, or electronic mail.

Mail: U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW, Room 2134LM, Attention: Jean Sonneman, Washington, DC 20240.

Fax: Jean Sonneman at 202–245–0050.

Electronic mail: Jean_Sonneman@blm.gov.

Please indicate “Attn: 1004–0168” regardless of the form of your comments.

FOR FURTHER INFORMATION CONTACT:

Dustin Wharton at 541–471–6659. Persons who use a telecommunication device for the deaf may call the Federal Relay Service at 1–800–877–8339, to leave a message for Mr. Wharton.

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR part 1320, which implement provisions of the PRA (44 U.S.C. 3501–3521), require that interested members of the public and affected agencies be given an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d) and 1320.12(a)). This notice identifies an information collection that the BLM plans to submit to OMB for approval. The PRA provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

The BLM will request a 3-year term of approval for this information collection activity. Comments are invited on: (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3)

ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany our submission of the information collection requests to OMB.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

The following information pertains to this request:

Title: Tramroads and Logging Roads (43 CFR part 2810).

OMB Control Number: 1004–0168.

Summary: The BLM Oregon State Office has authority under the Oregon and California Revested Lands Sustained Yield Management Act of 1937 (43 U.S.C. 2601 and 2602) and subchapter V of the Federal Land Policy and Management Act (43 U.S.C. 1761–1771) to grant rights-of-way to private landowners to transport their timber over roads controlled by the BLM. This information collection enables the BLM to calculate and collect appropriate fees for this use of public lands.

Frequency of Collection: Annually, biannually, quarterly, or monthly, depending on the terms of the pertinent right-of-way.

Forms: Form 2812–6, Report of Road Use.

Description of Respondents: Private landowners who hold rights-of-way for the use of BLM-controlled roads in western Oregon.

Estimated Annual Responses: 272.

Hours per Response: 8.

Estimated Annual Burden Hours: 2,176.

Estimated Annual Non-Hour Costs: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Jean Sonneman,

*Information Collection Clearance Officer,
Bureau of Land Management.*

[FR Doc. 2019–19937 Filed 9–13–19; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Third Point Offshore Fund, Ltd., et al.: Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a proposed Final Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in *United States of America v. Third Point Offshore Fund, Ltd., et al.*, Civil Action No. 1:19–cv–02593. On August 28, 2019, the United States filed a Complaint alleging that Third Point Offshore Fund, Ltd., Third Point Ultra Ltd., Third Point Partners Qualified L.P., and Third Point LLC violated the notice and waiting period requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. 18a (“HSR Act”), with respect to their acquisition of voting securities of DowDuPont Inc. The proposed Final Judgment, filed at the same time as the Complaint, requires the defendants to pay a civil penalty of \$609,810 and be subject to an injunction prohibiting the defendants from undertaking similar acquisitions without complying with notification and waiting period requirements of the HSR Act.

Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection on the Antitrust Division’s website at <http://www.justice.gov/atr> and at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, including the name of the submitter, and responses thereto, will be posted on the Antitrust Division’s website, filed with the Court, and, under certain circumstances, published in the **Federal Register**. Comments should be directed to Kenneth A. Libby, Special Attorney, United States, c/o Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580

(telephone: (202)326–2694; email: klubby@ftc.gov).

Patricia A. Brink,

Director of Civil Enforcement.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

United States of America, 450 Fifth Street NW, Washington, DC 20530, Plaintiff, v. Third Point Offshore Fund, LTD., c/o Cayman Corporate Center, 27 Hospital Road, George Town, Grand Cayman KY1-9008, Cayman Islands, Third Point Ultra LTD., c/o Maples Corporate Services (BVI) Ltd., Kingston Chambers, P.O. Box 173, Road Town, Tortola, British Virgin Islands, Third Point Partners Qualified L.P., Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, and, Third Point LLC, 390 Park Avenue, 19th Floor, New York, NY 10022, Defendants.

Civil Action No. 1:19-cv-02593-CJN

COMPLAINT FOR CIVIL PENALTIES AND INJUNCTIVE RELIEF FOR FAILURE TO COMPLY WITH THE PREMERGER REPORTING AND WAITING REQUIREMENTS OF THE HART-SCOTT RODINO ACT

The United States of America, Plaintiff, by its attorneys, acting under the direction of the Attorney General of the United States and at the request of the Federal Trade Commission, brings this civil antitrust action to obtain monetary relief in the form of civil penalties and injunctive relief against Defendants Third Point Offshore Fund, Ltd. (“Third Point Offshore”), Third Point Ultra Ltd. (“Third Point Ultra”), Third Point Partners Qualified L.P. (“Third Point Partners”) (collectively, “Defendant Funds”) and Third Point LLC (collectively with Defendant Funds, “Defendants”). Plaintiff alleges as follows:

INTRODUCTION

1. The Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. § 18a (“HSR Act” or “Act”) is an essential part of modern antitrust enforcement. It requires the buyer and the seller of voting securities or assets in excess of a certain value to notify the Department of Justice and the Federal Trade Commission and to observe a waiting period prior to consummating the acquisition. This waiting period provides the federal antitrust agencies with an opportunity to investigate and to seek an injunction to prevent the consummation of acquisitions that are likely to be anticompetitive.

2. Each Defendant Fund violated the HSR Act's notice and waiting requirements when it acquired voting securities of DowDuPont Inc. ("DowDuPont") on August 31, 2017, as a result of the consolidation of Dow Chemical Company ("Dow") and E.I. du Pont de Nemours and Company ("DuPont").

3. The Court should assess an appropriate civil penalty and injunctive relief for these violations of the HSR Act's requirements.

JURISDICTION AND VENUE

4. This Court has jurisdiction over Defendants and over the subject matter of this action pursuant to Section 7A(g) of the Clayton Act, 15 U.S.C. § 18a(g), and pursuant to 28 U.S.C. §§ 1331, 1337(a), 1345, and 1355, and over Defendants by virtue of Defendants' consent, in the Stipulation relating hereto, to the maintenance of this action and entry of the Final Judgment in this District.

5. Venue is properly based in this District by virtue of Defendants' consent, in the Stipulation relating hereto, to the maintenance of this action and entry of the Final Judgment in this District.

THE DEFENDANTS

6. Defendant Third Point Offshore is an offshore fund organized under the laws of the Cayman Islands with its registered office at Walkers Corporate Limited, Corporate Centre, 27 Hospital Road, George Town, Grand Cayman KY1-9008, Cayman Islands.

7. Defendant Third Point Ultra is an offshore fund organized under the laws of the British Virgin Islands with its registered office at Maples Corporate Services (BVI) Ltd., Kingston Chambers, P.O. Box 173, Road Town, Tortola, British Virgin Islands. The Investment Manager of Defendant Third Point Ultra has its office at 390 Park Avenue, 19th Floor, New York, NY 10022.

8. Defendant Third Point Partners is a limited partnership organized under the laws of the State of Delaware, with its principal place of business at Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801.

9. Defendant Third Point LLC is a limited liability company organized under the laws of the State of Delaware, with its principal place of business at 390 Park Avenue, 19th Floor, New York, NY 10022. Defendant Third Point LLC makes all the investment decisions on behalf of the Defendant Funds, including deciding whether to file notifications pursuant to the HSR Act and preparing the notification forms on behalf of each of the Defendant Funds.

10. Defendants are engaged in commerce, or in activities affecting commerce, within the meaning of Section 1 of the Clayton Act, 15 U.S.C. § 12, and Section 7A(a)(1) of the Clayton Act, 15 U.S.C. § 18a(a)(1). At all times relevant to this Complaint, each Defendant had total assets in excess of \$16.2 million.

OTHER ENTITIES

11. DowDuPont is a corporation organized under the laws of the State of Delaware with its principal place of business at 2030 Dow Center, Midland, MI 48674. DowDuPont is engaged in commerce, or in activities affecting commerce, within the meaning of Section 1 of the Clayton Act, 15 U.S.C. § 12, and Section 7A(a)(1) of the Clayton Act, 15 U.S.C. § 18a(a)(1). At all times relevant to this Complaint, DowDuPont had annual net sales in excess of \$161.5 million.

THE HART-SCOTT-RODINO ACT AND RULES

12. The HSR Act requires certain acquiring persons and certain persons whose voting securities or assets are acquired to file notifications with the federal antitrust agencies and to observe a waiting period before consummating certain acquisitions of voting securities or assets. 15 U.S.C. § 18a(a) and (b). The HSR Act's notification and waiting period requirements are intended to give the federal antitrust agencies prior notice of, and information about, proposed transactions. The waiting period is intended to provide the federal antitrust agencies with an opportunity to investigate a proposed transaction and to determine whether to seek an injunction to prevent the consummation of a transaction that may violate the antitrust laws.

13. The HSR Act's notification and waiting period requirements apply to acquisitions that meet the HSR Act's thresholds, which are adjusted annually. During the period of 2017 relevant to this Complaint, the HSR Act's reporting and waiting period requirements applied to transactions that would result in the acquiring person holding more than \$80.8 million of voting securities, non-corporate interests, or assets, if certain size of person tests were met, except for certain exempted transactions.

14. Pursuant to Section 7A(d)(2) of the HSR Act, 15 U.S.C. § 18a(d)(2), the Federal Trade Commission promulgated rules to carry out the purpose of the HSR Act. 16 C.F.R. §§ 801-03 ("HSR Rules"). The HSR Rules, among other things, define terms contained in the HSR Act.

15. Section 801.2(a) of the HSR Rules, 16 C.F.R. § 801.2(a), provides that "[a]ny person which, as a result of an acquisition, will hold voting securities" is deemed an "acquiring person."

16. Section 801.1(a)(1) of the HSR Rules, 16 C.F.R. § 801.1(a)(1), provides that the term "person" means "an ultimate parent entity and all entities which it controls directly or indirectly."

17. Section 801.1(a)(3) of the HSR Rules, 16 C.F.R. § 801.1(a)(3), provides that the term "ultimate parent entity" means "an entity which is not controlled by any other entity."

18. Section 801.2(d)(1)(i) of the HSR Rules, 16 C.F.R. § 801.2(d)(1)(i), provides that "mergers and consolidations are transactions subject to the act and shall be treated as acquisitions of voting securities."

19. Section 801.13(a) of the HSR Rules, 16 C.F.R. § 801.13(a), provides that "all voting securities of the issuer which will be held by the acquiring person after the consummation of an acquisition shall be deemed voting securities held as a result of the acquisition."

20. Section 802.21 of the HSR Rules, 16 C.F.R. § 802.21, provides that, when a person files under the HSR Act to acquire voting securities from an issuer and observes the waiting period, that person may acquire additional voting securities of the same issuer for five years after the end of the waiting period so long as it does not exceed any higher threshold as a result of the combined purchases.

21. Section 7A(g)(1) of the Clayton Act, 15 U.S.C. § 18a(g)(1), provides that any person, or any officer, director, or partner thereof, who fails to comply with any provision of the HSR Act is liable to the United States for a civil penalty for each day during which such person is in violation. For violations occurring on or after November 2, 2015, and assessed after August 1, 2016, the maximum amount of civil penalty is \$40,000 per day, pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Pub. L. 114-74, § 701 (further amending the Federal Civil Penalty Inflation Adjustment Act of 1990, 28 U.S.C. § 2461 note), and Federal Trade Commission Rule 1.98, 16 C.F.R. § 1.98, 81 Fed. Reg. 42,476 (June 30, 2016). As of January 22, 2018, the maximum penalty amount was further increased to \$41,484 per day for civil penalties assessed after that date. 83 Fed. Reg. 2903 (Jan. 22, 2018).

22. Section 7A(g)(2) of the Clayton Act, 15 U.S.C. § 18a(g)(2), provides that if any person fails substantially to comply with the notification requirement under the HSR Act, a

district court may grant such equitable relief as the court in its discretion determines necessary or appropriate, upon application of the Federal Trade Commission or the Assistant Attorney General.

VIOLATIONS ALLEGED

23. Plaintiff alleges and incorporates paragraphs 1 through 22 as if set forth fully herein.

24. On December 11, 2015, Dow and DuPont entered into a Merger Agreement pursuant to which Dow and DuPont would consolidate into a single company, to be called DowDuPont.

25. On June 10, 2016, Dow and DuPont issued their Final Proxy Statement/Prospectus for the consolidation. That document disclosed that, upon completion of the transaction, Dow and DuPont would cease to have their common stock publicly traded and that shareholders would own shares in DowDuPont and would not directly own any shares of Dow or DuPont.

26. On June 15, 2017, Dow and DuPont issued a joint press release stating that they had received antitrust clearance from the U.S. Department of Justice and that the transaction was on track to close in August 2017.

27. On August 4, 2017, Dow and DuPont issued a joint press release setting a closing date of August 31, 2017 for the transaction. The press release also stated that shares of Dow and DuPont would cease trading at the close of the New York Stock Exchange on August 31 and shares of DowDuPont will begin trading on September 1, 2017.

28. As of August 31, 2017, Defendant Third Point Offshore held 6,446,300 voting securities of Dow, Defendant Third Point Ultra held 4,376,813 voting securities of Dow, and Defendant Third Point Partners held 2,540,700 voting securities of Dow.

29. On August 31, 2017, Dow and DuPont completed the consolidation pursuant to the Merger Agreement of December 11, 2015, as amended on March 31, 2017. As a result of the consolidation, all holders of Dow and DuPont voting securities received voting securities of DowDuPont.

30. On August 31, 2017, each Defendant Fund received voting securities of DowDuPont valued in excess of \$80.8 million. Defendant Third Point Offshore acquired 6,446,300 voting securities of DowDuPont valued at approximately \$429.6 million. Defendant Third Point Ultra acquired 4,376,813 voting securities of DowDuPont valued at approximately \$291.7 million. Defendant Third Point Partners acquired 2,540,700 voting

securities of DowDuPont valued at approximately \$169.3 million.

31. Each Defendant Fund is its own ultimate parent entity within the meaning of the HSR Rules and had its own obligation to comply with the notification and waiting period requirements of the HSR Act and the HSR Rules.

32. The transactions described in Paragraph 30 were subject to the notification and waiting periods of the HSR Act and the HSR Rules. The HSR Act and HSR Rules in effect during the time period relevant to this proceeding required that each Defendant Fund file a notification and report form with the Department of Justice and the Federal Trade Commission and observe a waiting period before acquiring and holding an aggregate total amount of voting securities of DowDuPont in excess of \$80.8 million.

33. Previously, on April 7, 2014, each Defendant Fund had filed under the HSR Act to acquire voting securities of Dow and had observed the waiting period. Section 802.21 of the HSR Rules does not exempt the Defendant Funds' acquisitions of DowDuPont voting securities because DowDuPont is not the same issuer as Dow within the meaning of the HSR Rules. Among other things, for example, DowDuPont competes in additional lines of business from those in which Dow competed.

34. Although required to do so, each Defendant Fund failed to file and observe the waiting period prior to acquiring DowDuPont voting securities.

35. Defendant Third Point LLC had the power and authority to file a notification under the HSR Act on behalf of each of the Defendant Funds.

36. On November 8, 2017, each Defendant Fund filed a notification and report form under the HSR Act with the Department of Justice and the Federal Trade Commission reflecting their acquisitions of DowDuPont voting securities. The waiting period relating to these filings expired on December 8, 2017.

37. Each Defendant Fund was in violation of the HSR Act each day during the period beginning on August 31, 2017, and ending on December 8, 2017.

38. Defendants are currently under a court decree, also in the District Court of the District of Columbia, resulting from allegations that they previously violated the HSR Act in connection with acquisitions of voting securities of Yahoo! Inc. ("Yahoo"). Specifically, on August 24, 2015, the United States filed a complaint for equitable relief alleging that Defendants' acquisitions of Yahoo voting securities in August and

September of 2011 violated the HSR Act. At the same time, the United States filed a Stipulation signed by Defendants and a proposed Final Judgment that included provisions imposing certain injunctive relief against Defendants, including the requirement that Defendants maintain a compliance program. That Final Judgment was entered by that court on December 18, 2015. *U.S. v. Third Point Offshore Fund, Ltd., et al.*, Case 1:15-CV-01366.

REQUEST FOR RELIEF

Wherefore, the Plaintiff requests:

1. That the Court adjudge and decree that each Defendant Fund violated the HSR Act, 15 U.S.C. § 18a, as alleged in this Complaint and that each Defendant Fund was in violation of the Act on each day of the period from August 31, 2017, through December 8, 2017;

2. That the Court order each Defendant Fund to pay to the United States an appropriate civil penalty as provided by the HSR Act, 15 U.S.C. § 18a(g)(1), the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Pub. L. 114-74, § 701 (further amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461 note), and Federal Trade Commission Rule 1.98, 16 C.F.R. § 1.98, 84 FR 3980 (Feb. 14, 2019);

3. That the Court adjudge and decree that Defendant Third Point LLC had the power and authority to prevent the violations by the Defendant Funds and that relief against Third Point LLC is necessary and appropriate in order to ensure future compliance with the HSR Act by the Defendant Funds;

4. That the Court issue an appropriate injunction preventing future violations by Defendants as provided by the HSR Act, 15 U.S.C. § 18a(g)(2);

5. That the Court order such other and further relief as the Court may deem just and proper; and

6. That the Court award the Plaintiff its costs of this suit.

Dated: 8/28/19

FOR THE PLAINTIFF UNITED STATES OF AMERICA:

Makan Delrahim
Assistant Attorney General, Department of Justice, Antitrust Division, Washington, DC 20530.

Kenneth A. Libby,
Jennifer Lee,
Kelly Horne,
Special Attorneys.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

United States of America, Plaintiff, v. *Third Point Offshore Fund, LTD., Third Point Ultra LTD., Third Point Partners Qualified L.P., and Third Point LLC*, Defendants.

Civil Action No. 1:19-cv-02593-CJN

[PROPOSED] FINAL JUDGMENT

WHEREAS, the United States of America filed its Complaint on August 28, 2019, alleging that Defendants Third Point Offshore Fund, Ltd., Third Point Ultra Ltd., and Third Point Partners Qualified L.P. (collectively, “Third Point Funds” or “Defendant Funds”) violated Section 7A of the Clayton Act (15 U.S.C. § 18a, commonly known as the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the “HSR Act”)), and the United States and Defendants Third Point Funds and Third Point LLC (collectively, “Defendants”), by their respective attorneys, have consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against, or any admission by, any party regarding any such issue of fact or law;

AND WHEREAS Defendants agree to be bound by the provisions of this Final Judgment pending its approval by the Court;

NOW, THEREFORE, before any testimony is taken, and without trial or adjudication of any issue of fact or law, and upon the consent of the parties, it is ORDERED, ADJUDGED AND DECREED;

I. JURISDICTION

This Court has jurisdiction over the subject matter of this action. The Defendants consent solely for the purpose of this action and the entry of this Final Judgment that this Court has jurisdiction over each of the parties to this action and that the Complaint states a claim upon which relief may be granted against Defendants under Section 7A of the Clayton Act, as amended (15 U.S.C. § 18a).

II. DEFINITIONS

As used in this Final Judgment:

(A) “Consolidation” shall have the meaning of “consolidation” as used in 16 C.F.R. § 801.2.

(B) “Consolidated Issuer” means an Issuer that is formed by a Consolidation.

(C) “*De Minimis* Exemption” means a modification to the HSR Act or any Regulation thereunder that exempts from the reporting and waiting

requirements of the HSR Act the acquisition of Voting Securities of an Issuer by any Acquiring Person, or by an Acquiring Person that is not a competitor of the Issuer or that otherwise meets specified criteria, on the basis that the acquisition results in the Acquiring Person’s holding not more than, or less than, a specified percentage of the outstanding Voting Securities of the Issuer.

(D) “Issuer” means a legal entity that issues Voting Securities.

(E) “Person” means any natural person.

(F) “Regulation” shall mean any rule, regulation, statement, or interpretation under the HSR Act that has legal effect with respect to the implementation or application of the HSR Act or any section within 16 C.F.R. §§ 801-803.

(G) “Third Point LLC” means Defendant Third Point LLC, a limited liability company organized under the laws of the State of Delaware, with its principal place of business at 390 Park Avenue, 19th Floor, New York, NY 10022; its successors and assigns; and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

(H) “Third Point Offshore Fund, Ltd.” means Defendant Third Point Offshore Fund, Ltd., an exempted company organized under the laws of the Cayman Islands, with its registered office at Walkers Corporate Limited, Corporate Centre, 27 Hospital Road, George Town, Grand Cayman KY1-9008, Cayman Islands; its successors and assigns; and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

(I) “Third Point Partners Qualified L.P.” means Defendant Third Point Partners Qualified L.P., a limited partnership organized under the laws of the State of Delaware, with its registered address at Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801; its successors and assigns; and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

(J) “Third Point Ultra Ltd.” means Defendant Third Point Ultra Ltd., an international business company organized under the laws of the British Virgin Islands, with its registered office at Maples Corporate Services (BVI) Ltd., Kingston Chambers, P.O. Box 173, Road Town, Tortola, British Virgin Islands; its successors and assigns; and its subsidiaries, divisions, groups, affiliates, partnerships, and joint

ventures, and their directors, officers, managers, agents, and employees.

(K) Other capitalized terms have the meanings as defined in the HSR Act and Regulations promulgated thereunder, 16 C.F.R. §§ 801-803.

III. APPLICABILITY

(A) This Final Judgment applies to all Defendants, as defined above, and to all other Persons and entities who are in active concert or participation with any of the foregoing with respect to conduct prohibited in Paragraph IV when the relevant Persons or entities have received actual notice of this Final Judgment by personal service or otherwise.

(B) Pursuant to Rule 506(d)(2)(iii), 17 C.F.R. § 230.506(d)(2)(iii), as promulgated under the Securities Act of 1933, 15 U.S.C. § 77a, *et seq.*, disqualification under paragraph (d)(1) of Rule 506, 17 C.F.R. § 230.506(d)(1), shall not arise as a consequence of the entry of this Final Judgment or of the entry of any other order or judgment in this action.

IV. PROHIBITED CONDUCT

Each Defendant is enjoined from acquiring Voting Securities of a Consolidated Issuer in exchange for Voting Securities of any Issuer that was a party to the Consolidation when:

(A) The acquisition of the Voting Securities of the Consolidated Issuer would meet the notification requirements of the HSR Act;

(B) Defendant’s acquisition of such Voting Securities would not be exempt from the reporting and waiting requirements of the HSR Act; and

(C) Defendant has not fulfilled the reporting and waiting requirements of the HSR Act with respect to the acquisition of such Voting Securities.

V. CIVIL PENALTY

(A) Judgment is hereby entered in this matter in favor of Plaintiff and against the Defendants and, pursuant to Section 7A(g)(1) of the Clayton Act, 15 U.S.C. § 18a(g)(1), and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Pub. L. 114-74 § 701, codified at 28 U.S.C. § 1 (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101-410 (codified at 28 U.S.C. § 2461 note)), and Federal Trade Commission Rule 1.98, 16 C.F.R. § 1.98, 81 Fed. Reg. 42, 476 (June 30, 2016), Defendant Funds are hereby ordered, jointly and severally, to pay a single civil penalty in the amount of six hundred nine thousand, eight hundred ten dollars and no cents (\$609,810.00). Payment of the civil penalty ordered hereby shall be made by wire transfer of

funds or cashier's check. If the payment is made by wire transfer, Defendant Funds shall contact Janie Ingalls of the Antitrust Division's Antitrust Documents Group at (202) 514-2481 for instructions before making the transfer. If the payment is made by cashier's check, the check shall be made payable to the United States Department of Justice and delivered to:

Janie Ingalls
United States Department of Justice
Antitrust Division, Antitrust Documents Group
450 5th Street, NW
Suite 1024
Washington, D.C. 20530

(B) Defendant Funds shall pay the full amount of the civil penalty within thirty (30) days of entry of this Final Judgment. In the event of a default or delay in payment, interest at the rate of 18 percent per annum shall accrue thereon from the date of the default or delay to the date of payment.

VI. COMPLIANCE INSPECTION

(A) For the purpose of determining or securing compliance with this Final Judgment, and subject to any legally recognized privilege, duly authorized representatives of the United States, including agents and consultants retained by the United States, shall, upon written request of a duly authorized representative of the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to Defendants, be permitted:

(1) access during Defendants' office hours to inspect and copy, or at the option of the United States, to require Defendants to provide electronic copies of all books, ledgers, accounts, records, data, and documents in the possession, custody, or control of Defendants, relating to any matters contained in this Final Judgment; and

(2) to interview, either informally or on the record, Defendants' directors, officers, employees, agents, or other Persons, who may have their individual counsel present, regarding such matters. The interviews shall be subject to the reasonable convenience of the interviewee and without restraint or interference by Defendants.

(B) Upon written request of a duly authorized representative of the Assistant Attorney General in charge of the Antitrust Division, Defendants shall submit written reports or responses to written interrogatories, under oath if requested, relating to any of the matters contained in this Final Judgment as may be requested.

(C) No information or documents obtained by the means provided in this

Final Judgment shall be divulged by the United States to any person other than an authorized representative of the executive branch of the United States or of the Federal Trade Commission, except in the course of legal proceedings to which the United States is a party (including grand jury proceedings), or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

(D) If, at the time information or documents are furnished by Defendants to the United States, Defendants represent and identify in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(1) of the Federal Rules of Civil Procedure, and Defendants mark each pertinent page of such material, "Subject to claim of protection under Rule 26(c)(1) of the Federal Rules of Civil Procedure," then the United States shall give Defendants ten (10) calendar days' notice prior to divulging such material in any legal proceeding (other than a grand jury proceeding).

VII. RETENTION OF JURISDICTION

This Court retains jurisdiction to enable any party to this Final Judgment to apply to this Court at any time for such further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify or terminate any of its provisions, to enforce compliance, and to punish any violations of its provisions.

VIII. ENFORCEMENT OF FINAL JUDGMENT

(A) The United States retains and reserves all rights to enforce the provisions of this Final Judgment, including the right to seek an order of contempt from this Court. Defendants agree that in any civil contempt action, any motion to show cause, or any similar action brought by the United States regarding an alleged civil violation of this Final Judgment, the United States may establish a civil violation of the decree and the appropriateness of any remedy therefor by a preponderance of the evidence, and Defendants waive any argument that a different standard of proof should apply.

(B) The Final Judgment should be interpreted to give full effect to the procompetitive purposes of the antitrust laws, including the HSR Act and Regulations promulgated thereunder. Defendants agree that they may be held in contempt of, and that the Court may enforce, any provision of this Final

Judgment that, as interpreted by the Court in light of these procompetitive principles and applying ordinary tools of interpretation, is stated specifically and in reasonable detail, whether or not it is clear and unambiguous on its face. In any such interpretation, the terms of this Final Judgment should not be construed against either party as the drafter.

(C) In any enforcement proceeding in which the Court finds that the Defendants have violated this Final Judgment, the United States may apply to the Court for a one-time extension of this Final Judgment, together with such other relief as may be appropriate. In connection with any successful effort by the United States to enforce this Final Judgment against a Defendant, whether litigated or resolved prior to litigation, that Defendant agrees to reimburse the United States for the fees and expenses of its attorneys, as well as any other costs including experts' fees, incurred in connection with that enforcement effort, including in the investigation of the potential violation.

IX. EXPIRATION OF FINAL JUDGMENT

Unless the Court grants an extension, this Final Judgment shall expire five (5) years from the date of its entry, except that:

(A) after three (3) years from the date of its entry, this Final Judgment may be terminated upon notice by the United States to the Court and Defendants that the civil penalty has been paid and that the continuation of the Final Judgment no longer is necessary or in the public interest; or

(B) if, during any part of the term of this Final Judgment, a *De Minimis* Exemption becomes legally effective, then this Final Judgment may be terminated only upon notice by the United States to the Court that the continuation of the Final Judgment no longer is necessary or in the public interest. It shall be in the sole discretion of the United States whether to seek such termination after receiving a request to do so from Defendants.

X. COSTS

Each party shall bear its own costs.

XI. PUBLIC INTEREST DETERMINATION

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16, including making available to the public copies of this Final Judgment, the Competitive Impact Statement, any comments thereon, and

the United States' responses to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and responses to comments filed with the Court, entry of this Final Judgment is in the public interest.

DATED: _____

Court approval subject to the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16

United States District Judge

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

United States of America c/o Department of Justice, Plaintiff, v. Third Point Offshore Fund, Ltd. c/o Cayman Corporate Center, Third Point Ultra Ltd. c/o Maples Corporate Services (BVI) Ltd., Third Point Partners Qualified L.P. Corporation Trust Center, and Third Point LLC, Defendants.

Civil Action No. 1:19-cv-02593-CJN

COMPETITIVE IMPACT STATEMENT

Plaintiff United States of America ("United States"), pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act ("APPA"), 15 U.S.C. § 16(b)-(h), files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

I. NATURE AND PURPOSE OF THE PROCEEDING

On August 28, 2019, the United States filed a Complaint against Defendants Third Point Offshore Fund, Ltd. ("Third Point Offshore"), Third Point Ultra, Ltd. ("Third Point Ultra"), Third Point Partners Qualified L.P. ("Third Point Partners") (collectively, "Defendant Funds") and Third Point LLC (collectively with Defendant Funds, "Defendants"), related to Defendant Funds' acquisitions of voting securities of DowDuPont Inc. ("DowDuPont") on August 31, 2017. The Complaint alleges that Defendants violated Section 7A of the Clayton Act, 15 U.S.C. § 18a, commonly known as the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "HSR Act"). The HSR Act provides that "no person shall acquire, directly or indirectly, any voting securities or assets of any person" exceeding certain thresholds until that person has filed pre-acquisition notification and report forms with the Department of Justice and the Federal Trade Commission (collectively, the "federal antitrust agencies" or "agencies") and the post-filing waiting period has expired. 15 U.S.C. § 18a(a). A key purpose of the notification and waiting period requirements is to protect consumers and competition from potentially anticompetitive

transactions by providing the agencies an opportunity to conduct an antitrust review of proposed transactions before they are consummated.

The Complaint alleges that each Defendant Fund acquired voting securities of DowDuPont in excess of the then-applicable statutory threshold (\$80.8 million at the time of acquisition) without making the required pre-acquisition HSR Act filings with the agencies and without observing the waiting period, and that each Defendant Fund and DowDuPont met the applicable statutory size of person thresholds.

At the same time the Complaint was filed in the present action, the United States also filed a Stipulation and proposed Final Judgment that eliminates the need for a trial in this case. The proposed Final Judgment is designed to address the violation alleged in the Complaint and deter Defendants' HSR Act violations and deter violations by similarly situated entities in the future. Under the proposed Final Judgment, Defendants must pay a civil penalty to the United States in the amount of \$609,810 and are subject to an injunction against future violations.

The United States and Defendants have stipulated that the proposed Final Judgment may be entered after compliance with the APPA, unless the United States first withdraws its consent. Entry of the proposed Final Judgment would terminate this case, except that the Court would retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and punish violations thereof.

II. DESCRIPTION OF THE EVENTS GIVING RISE TO THE ALLEGED VIOLATION

Third Point LLC is a New York-based financial investment firm managed by Daniel S. Loeb.¹ Started in 1995 with approximately \$3.3 million, Third Point LLC has grown quickly over the years and, in 2014, managed approximately \$16 billion through a variety of funds, including Third Point Offshore, Third Point Ultra, and Third Point Partners, all of which are managed centrally by Mr. Loeb. At all times relevant to the Complaint, each Defendant Fund had assets in excess of \$16.2 million. At all times relevant to the Complaint,

¹ Mr. Loeb closely controls Third Point LLC and its funds. He is not, however, the ultimate parent entity ("UPE") within the meaning of the HSR Rules of any of the Third Point funds that made the relevant acquisitions of DowDuPont.

DowDuPont had sales in excess of \$161.5 million.

On December 11, 2015, the Dow Chemical Company ("Dow") and E.I. du Pont de Nemours and Company ("DuPont") entered into a Merger Agreement pursuant to which Dow and DuPont would consolidate into a single company, to be called DowDuPont Inc. On June 10, 2106, Dow and DuPont issued their Final Proxy Statement/Prospectus for the consolidation. That document disclosed that, upon completion of the transaction, Dow and DuPont would cease to have their common stock publicly traded and that shareholders would own shares in DowDuPont and would not directly own any shares of Dow and/or DuPont. On June 15, 2017, Dow and DuPont issued a joint press release stating that they had received antitrust clearance from the U.S. Department of Justice and that the transaction was on track to close in August 2017. On August 4, 2017, Dow and DuPont issued a joint press release setting the closing date of August 31, 2017 for the transaction. The press release also stated that shares of Dow and DuPont would cease trading at the close of the New York Stock Exchange on August 31, and shares of DowDuPont will begin trading on September 1, 2017.

As of August 31, 2017, Defendant Third Point Offshore held 6,446,300 voting securities of Dow; Defendant Third Point Ultra held 4,376,813 voting securities of Dow; and Defendant Third Point Partners held 2,540,700 voting securities of Dow. On August 31, 2017, Dow and DuPont completed the consolidation pursuant to a Merger Agreement dated December 11, 2015, as amended on March 31, 2017. As a result of the consolidation, all holders of Dow and DuPont voting securities received voting securities of DowDuPont.

On August 31, 2017, each Defendant Fund received voting securities of DowDuPont valued in excess of \$80.8 million. Defendant Third Point Offshore acquired 6,446,300 voting securities of DowDuPont valued at approximately \$429.6 million. Defendant Third Point Ultra acquired 4,376,813 voting securities of DowDuPont valued at approximately \$291.7 million. Defendant Third Point Partners acquired 2,540,700 voting securities of DowDuPont valued at approximately \$169.3 million. Each Defendant Fund is its own UPE within the meaning of the HSR Rules and had its own obligation to comply with the notification and waiting period requirements of the HSR Act and the HSR Rules.

The transactions described above were subject to the notification and waiting periods of the HSR Act. The

HSR Act and the thresholds in effect during the time period relevant to this proceeding required that each Defendant Fund file a notification and report form with the Department of Justice and the Federal Trade Commission and observe a waiting period before acquiring and holding an aggregate total amount of voting securities of DowDuPont in excess of \$80.8 million.

Previously, on April 7, 2014, each Defendant Fund had filed under the HSR Act to acquire voting securities of Dow and had observed the waiting period. Under Section 802.21 of the HSR Rules, Defendants were permitted for the subsequent five years to acquire additional voting securities of Dow without making another HSR Act filing so long as they did not exceed the next-higher threshold. However, Section 802.21 does not exempt Defendant Funds' acquisitions of DowDuPont voting securities because DowDuPont is not the same issuer as Dow within the meaning of the HSR Rules. Among other things, DowDuPont competes in additional lines of business from those in which Dow competed.

Although required to do so, each Defendant Fund failed to file and observe the waiting period prior to acquiring DowDuPont voting securities. Defendant Third Point LLC had the power and authority to file a notification under the HSR Act on behalf of each of Defendant Funds.

On November 8, 2017, each Defendant Fund filed a notification and report form under the HSR Act with the Department of Justice and the Federal Trade Commission to cover their acquisitions of DowDuPont voting securities. The waiting period relating to these filings expired on December 8, 2017. Each Defendant Fund was in violation of the HSR Act each day during the period beginning on August 31, 2017, and ending on December 8, 2017.

The Complaint further alleges that Defendants' August 31, 2017, HSR Act violation was not the first time Defendants had failed to observe the HSR Act's notification and waiting period requirements. Defendants are currently under a court decree resulting from allegations that they previously violated the HSR Act in connection with acquisitions of voting securities of Yahoo! Inc. ("Yahoo"). Specifically, on August 24, 2015, the United States filed a complaint for equitable relief alleging that Defendants' acquisitions of Yahoo voting securities in August and September 2011 violated the HSR Act. At the same time, the United States filed a Stipulation signed by Defendants and

a proposed Final Judgment that would impose certain injunctive relief against Defendants, including the requirement that Defendants maintain a compliance program. The Final Judgment was entered by the court on December 18, 2015.

III. EXPLANATION OF THE PROPOSED FINAL JUDGMENT

The proposed Final Judgment imposes a \$609,810 civil penalty and an injunction against future violations designed to address the violation alleged in the Complaint and deter Defendants and others from violating the HSR Act. The United States adjusted the penalty downward from the maximum permitted under the HSR Act because the violation was inadvertent, Defendants promptly self-reported the violation after discovery, and Defendants are willing to resolve the matter by consent decree and avoid prolonged investigation and litigation. The relief will have a beneficial effect on competition because the agencies will be properly notified of future acquisitions, in accordance with the law. At the same time, neither the penalty nor the injunctive relief will have any adverse effect on competition.

IV. REMEDIES AVAILABLE TO POTENTIAL PRIVATE LITIGANTS

There is no private antitrust action for HSR Act violations; therefore, entry of the proposed Final Judgment will neither impair nor assist the bringing of any private antitrust action.

V. PROCEDURES AVAILABLE FOR MODIFICATION OF THE PROPOSED FINAL JUDGMENT

The United States and Defendants have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least sixty (60) days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within sixty (60) days of the date of publication of this Competitive Impact Statement in the *Federal Register*, or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the United States

Department of Justice, which remains free to withdraw its consent to the proposed Final Judgment at any time prior to the Court's entry of judgment. The comments and the response of the United States will be filed with the Court. In addition, comments will be posted on the U.S. Department of Justice, Antitrust Division's internet website and, under certain circumstances, published in the *Federal Register*. Written comments should be submitted to:

Kenneth A. Libby
Special Attorney, United States
c/o Federal Trade Commission
600 Pennsylvania Avenue, NW
CC-8404
Washington, DC 20580
Email: klibby@ftc.gov

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. ALTERNATIVES TO THE PROPOSED FINAL JUDGMENT

The United States considered, as an alternative to the proposed Final Judgment, a full trial on the merits against Defendants. The United States is satisfied, however, that the proposed relief is an appropriate remedy in this matter. Given the facts of this case, including Defendants' self-reporting of the violation and willingness to settle this matter, the United States is satisfied that the proposed civil penalty and injunction are sufficient to address the violation alleged in the Complaint and to deter violations by similarly situated entities in the future, without the time, expense, and uncertainty of a full trial on the merits.

VII. STANDARD OF REVIEW UNDER THE APPA FOR THE PROPOSED FINAL JUDGMENT

The Clayton Act, as amended by the APPA, requires that proposed consent judgments in antitrust cases brought by the United States be subject to a 60-day comment period, after which the court shall determine whether entry of the proposed Final Judgment "is in the public interest." 15 U.S.C. § 16(e)(1). In making that determination, the court, in accordance with the statute as amended in 2004, is required to consider:

(A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing

upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and (B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. § 16(e)(1)(A) & (B). In considering these statutory factors, the court's inquiry is necessarily a limited one as the government is entitled to "broad discretion to settle with the defendant within the reaches of the public interest." *United States v. Microsoft Corp.*, 56 F.3d 1448, 1461 (D.C. Cir. 1995); *United States v. U.S. Airways Grp., Inc.*, 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (explaining that the "court's inquiry is limited" in Tunney Act settlements); *United States v. InBev N.V./S.A.*, No. 08-1965 (JR), 2009 U.S. Dist. LEXIS 84787, at *3 (D.D.C. Aug. 11, 2009) (noting that the court's review of a consent judgment is limited and only inquires "into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanism to enforce the final judgment are clear and manageable").

As the United States Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations in the government's complaint, whether the Final Judgment is sufficiently clear, whether its enforcement mechanisms are sufficient, and whether the Final Judgment may positively harm third parties. *See Microsoft*, 56 F.3d at 1458-62. With respect to the adequacy of the relief secured by the Final Judgment, a court may not "engage in an unrestricted evaluation of what relief would best serve the public." *United States v. BNS, Inc.*, 858 F.2d 456, 462 (9th Cir. 1988) (quoting *United States v. Bechtel Corp.*, 648 F.2d 660, 666 (9th Cir. 1981)); *see also Microsoft*, 56 F.3d at 1460-62; *United States v. Alcoa, Inc.*, 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *InBev*, 2009 U.S. Dist. LEXIS 84787, at *3. Instead:

[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to

determine not whether a particular decree is the one that will best serve society, but whether the settlement is "within the reaches of the public interest." More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted).²

The United States' predictions with respect to the efficacy of the remedy are to be afforded deference by the Court. *See, e.g., Microsoft*, 56 F.3d at 1461 (recognizing courts should give "due respect to the Justice Department's . . . view of the nature of its case"); *United States v. Iron Mountain, Inc.*, 217 F. Supp. 3d 146, 152-53 (D.D.C. 2016) ("In evaluating objections to settlement agreements under the Tunney Act, a court must be mindful that [t]he government need not prove that the settlements will perfectly remedy the alleged antitrust harms[:]; it need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms." (internal citations omitted)); *United States v. Republic Servs., Inc.*, 723 F. Supp. 2d 157, 160 (D.D.C. 2010) (noting "the deferential review to which the government's proposed remedy is accorded"); *United States v. Archer-Daniels-Midland Co.*, 272 F. Supp. 2d 1, 6 (D.D.C. 2003) ("A district court must accord due respect to the government's prediction as to the effect of proposed remedies, its perception of the market structure, and its view of the nature of the case."). The ultimate question is whether "the remedies [obtained in the Final Judgment are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest.'" *Microsoft*, 56 F.3d at 1461 (quoting *United States v. Western Elec. Co.*, 900 F.2d 283, 309 (D.C. Cir. 1990)).

Moreover, the court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its complaint, and does not authorize the court to "construct [its] own hypothetical case and then evaluate the decree against that case." *Microsoft*, 56 F.3d at 1459; *see also U.S. Airways*, 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed

settlements are reasonable); *InBev*, 2009 U.S. Dist. LEXIS 84787, at *20 ("the 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged"). Because the "court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place," it follows that "the court is only authorized to review the decree itself," and not to "effectively redraft the complaint" to inquire into other matters that the United States did not pursue. *Microsoft*, 56 F.3d at 1459-60.

In its 2004 amendments to the APPA,³ Congress made clear its intent to preserve the practical benefits of utilizing consent Final Judgments in antitrust enforcement, adding the unambiguous instruction that "[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene." 15 U.S.C. § 16(e)(2); *see also U.S. Airways*, 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language explicitly wrote into the statute what Congress intended when it first enacted the Tunney Act in 1974. As Senator Tunney explained: "[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process." 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). "A court can make its public interest determination based on the competitive impact statement and response to public comments alone." *U.S. Airways*, 38 F. Supp. 3d at 76 (citing *United States v. Enova Corp.*, 107 F. Supp. 2d 10, 17 (D.D.C. 2000)).

VIII. DETERMINATIVE DOCUMENTS

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Date: August 28, 2019
Respectfully submitted,

Kenneth A. Libby,
Special Attorney,
U.S. Department of Justice,
Antitrust Division,
c/o Federal Trade Commission

² *See also BNS*, 858 F.2d at 464 (holding that the court's "ultimate authority under the [APPA] is limited to approving or disapproving the consent decree"); *United States v. Gillette Co.*, 406 F. Supp. 713, 716 (D. Mass. 1975) (noting that, in this way, the court is constrained to "look at the overall picture not hypercritically, nor with a microscope, but with an artist's reducing glass").

³ Pub. L. 108-237, § 221.

600 Pennsylvania Avenue NW,
Washington, DC 20580,
Phone: (202) 326-2694,
Email: klibby@ftc.gov.

[FR Doc. 2019-19919 Filed 9-13-19; 8:45 am]

BILLING CODE 67500-01-P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On September 10, 2019, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of Arizona in the lawsuit entitled *United States v. Nouryon Functional Chemicals LLC f/k/a Akzo Nobel Functional Chemicals LLC*, Civil Action No. 1:19-cv-00626.

The United States filed this civil enforcement action under the federal Clean Air Act. The United States' complaint seeks injunctive relief and civil penalties for violations of the regulations that govern emissions from the defendant's sulfuric acid manufacturing facility in Axis, Alabama. The proposed consent decree resolves the claims alleged in the complaint and requires the defendant to perform injunctive relief that will significantly reduce emissions of sulfur dioxide and sulfuric acid mist, as well as other air pollutants, at its facility, and to pay a civil penalty of \$300,000. Additionally, the proposed consent decree requires the defendant to perform an environmental mitigation project that will benefit communities adversely affected by pollution from its facility.

The publication of this notice opens a period for public comment on the proposed consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States v. Akzo Nobel Functional Chemicals LLC*, D.J. Ref. No. 90-5-2-1-11404. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By email	pubcomment-ees.enrd@usdoj.gov .
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

During the public comment period, the proposed consent decree may be

examined and downloaded at this Justice Department website: <http://www.justice.gov/enrd/consent-decrees>. We will provide a paper copy of the proposed consent decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

Please enclose a check or money order for \$16.00 (25 cents per page reproduction cost) payable to the United States Treasury.

Henry Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2019-19940 Filed 9-13-19; 8:45 am]

BILLING CODE 4410-15-P

DEPARTMENT OF JUSTICE

[OMB Number 1121-0260]

Agency Information Collection Activities: Proposed eCollection eComments Requested; Revision of a Currently Approved Collection: 2020 Police Public Contact Survey (PPCS)

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 30-Day Notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This notice is being published to seek public comments on a change to the survey instrument proposed for the 2020 collection.

DATES: Comments are encouraged and will be accepted for 30 days until October 16, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Elizabeth Davis, Statistician, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531 (email: Elizabeth.Davis@usdoj.gov; telephone: 202-305-2667).

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should

address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a currently approved collection.

(2) *The Title of the Form/Collection:* 2020 Police Public Contact Survey.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number for the questionnaire is PPCS-1. The applicable component within the Department of Justice is the Bureau of Justice Statistics, in the Office of Justice Programs.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Respondents will be persons 16 years or older living in households located throughout the United States sampled for the National Crime Victimization Survey (NCVS). The PPCS will be conducted as a supplement to the NCVS in all sample households for a six (6) month period. The PPCS is typically conducted about every three years, with the last administration occurring in 2018. BJS is conducting the next PPCS one year ahead of schedule, to include an item on how residents reacted during police contact that was not asked in 2018, but was asked in previous iterations of the survey. The PPCS is one component of the BJS effort to fulfill the mandate set forth by the Violent Crime Control and Law Enforcement Act of 1994 to collect, evaluate, and publish data on the use of excessive force by law enforcement personnel. The goal of the collection is to report national statistics that provide

a better understanding of the types, frequency, and outcomes of contacts between the police and the public, public perceptions of police behavior during the contact, and the conditions under which police force may be threatened or used. BJS plans to publish this information in reports and reference it when responding to queries from the U.S. Congress, Executive Office of the President, the U.S. Supreme Court, state officials, international organizations, researchers, students, the media, and others interested in criminal justice statistics.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimate of the total number of respondents is 108,806. About 75% of respondents (81,713) will have no police contact and will complete the short interview with an average burden of four minutes. Among the 25% of respondents (27,093) who experienced police contact, the time to ask the detailed questions regarding the nature of the contact is estimated to take an average of 8 minutes. Respondents will be asked to respond to this survey only once during the six-month period. The burden estimate is based on data from the 2018 administration of the PPCS.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 9,060 total burden hours associated with this collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: September 10, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019-19889 Filed 9-13-19; 8:45 am]

BILLING CODE 4410-18-P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Occupational Safety and Health Administration Alliance Program Office of the Secretary

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting the Occupational

Safety and Health Administration (OSHA) sponsored information collection request (ICR) proposal titled, "Occupational Safety and Health Administration Alliance Program," to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995. Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before October 16, 2019.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* website at http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201902-1218-001 (this link will only become active on the day following publication of this notice) or by contacting Frederick Licari by telephone at 202-693-8073, TTY 202-693-8064, (this is not a toll-free number) or by email at DOL_PRA_PUBLIC@dol.gov.

Submit comments about this request by mail to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL-OSHA, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503; by Fax: 202-395-5806 (this is not a toll-free number); or by email: OIRA_submission@omb.eop.gov. Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW, Washington, DC 20210; or by email: DOL_PRA_PUBLIC@dol.gov.

FOR FURTHER INFORMATION CONTACT: Frederick Licari by telephone at 202-693-8073, TTY 202-693-8064, (these are not toll-free numbers) or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: This ICR seeks PRA authority for the Occupational Safety and Health Administration Alliance Program information collection. OSHA's Alliance Program is a structure for working with groups that are committed to worker safety and health. The program enables OSHA to enter into a voluntary cooperative relationship with industry, labor and other groups to improve workplace safety and health, prevent workplace fatalities, injuries and illnesses, and to reach employers and workers that OSHA may not otherwise

reach through traditional methods. OSHA collects information from organizations that are signatories to an Alliance agreement through meetings, informal conversations and data forms. OSHA will use the collected information to develop Alliance agreements, support Alliance activities and Alliance agreement objectives, and develop annual and program-wide reports. Occupational Safety and Health Act of 1970 section (2)(b)(1) authorizes this information collection. *See* 29 U.S.C. 651(2)(b)(1).

This proposed information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB, under the PRA, approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. For additional information, see the related notice published in the **Federal Register** on June 21, 2018 (83 FR 28868).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty-(30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB ICR Reference Number 201902-1218-001. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL-OSHA.

Title of Collection: Occupational Safety and Health Administration Alliance Program.

OMB ICR Reference Number: 201902–1218–001.

Affected Public: Private Sector—businesses or other for-profits, State, Local, and Tribal Governments.

Total Estimated Number of Respondents: 250.

Total Estimated Number of Responses: 4,993.

Total Estimated Annual Time Burden: 14,122 hours.

Total Estimated Annual Other Costs Burden: \$0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: September 10, 2019.

Frederick Licari,

Departmental Clearance Officer.

[FR Doc. 2019–19909 Filed 9–13–19; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Technical Advisory Committee; Request for Nominations

AGENCY: Bureau of Labor Statistics (BLS).

ACTION: Request for nominations to the BLS Technical Advisory Committee.

SUMMARY: The BLS is soliciting new members for the Technical Advisory Committee (TAC). Five current membership terms expire on April 12, 2020. The TAC provides advice to the Bureau of Labor Statistics on technical aspects of data collection and the formulation of economic measures and makes recommendations on areas of research. On some technical issues there are differing views, and receiving feedback at public meetings provides BLS with the opportunity to consider all viewpoints. The Committee will consist of 16 members and will be chosen from a cross-section of economists, statisticians, and behavioral scientists who represent a balance of expertise. The economists will have research experience with technical issues related to BLS data and will be familiar with employment and unemployment statistics, price index numbers, compensation measures, productivity measures, occupational and health statistics, or other topics relevant to BLS data series. The statisticians will be familiar with sample design, data analysis, computationally intensive statistical methods, non-sampling errors, or other areas which are relevant to BLS work. The behavioral scientists will be familiar with questionnaire

design, usability, or other areas of survey development. BLS invites persons interested in serving on the TAC to submit their names for consideration for committee membership.

DATES: Nominations for the TAC membership should be postmarked October 16, 2019.

ADDRESSES: Nominations for the TAC membership should be sent to: Commissioner William Beach, U.S. Bureau of Labor Statistics, 2 Massachusetts Avenue NE, Room 4040, Washington, DC 20212.

FOR FURTHER INFORMATION CONTACT: Lucy Eldridge, Associate Commissioner, U.S. Bureau of Labor Statistics, 2 Massachusetts Avenue NE, Office of Productivity and Technology, Room 2150, Washington, DC 20212. Telephone: 202–691–5600. This is not a toll free number. Email: advisorycommittees@bls.gov.

SUPPLEMENTARY INFORMATION: BLS intends to renew memberships in the TAC for another three years. The Bureau often faces highly technical issues while developing and maintaining the accuracy and relevancy of its data on employment and unemployment, prices, productivity, and compensation and working conditions. These issues range from how to develop new measures to how to make sure that existing measures account for the ever-changing economy. The BLS presents issues and then draws on the specialized expertise of Committee members representing specialized fields within the academic disciplines of economics, statistics and survey design. Committee members are also invited to bring to the attention of BLS issues that have been identified in the academic literature or in their own research.

The TAC was established to provide advice to the Commissioner of Labor Statistics on technical topics selected by the BLS. Responsibilities include, but are not limited to providing comments on papers and presentations developed by BLS research and program staff, conducting research on issues identified by BLS on which an objective technical opinion or recommendation from outside of BLS would be valuable, recommending BLS conduct internal research projects to address technical problems with BLS statistics that have been identified in the academic literature, participating in discussions of areas where the types or coverage of economic statistics could be expanded or improved and areas where statistics are no longer relevant, and establishing working relationships with professional associations with an interest in BLS

statistics, such as the American Statistical Association and the American Economic Association.

Nominations: BLS is looking for committed TAC members who have a strong interest in, and familiarity with, BLS data. The Agency is looking for nominees who use and have a comprehensive understanding of economic statistics. The U.S. Bureau of Labor Statistics is committed to bringing greater diversity of thought, perspective, and experience to its advisory committees. Nominees from all races, gender, age, and disabilities are encouraged to apply. Interested persons may nominate themselves or may submit the name of another person who they believe to be interested in and qualified to serve on the TAC. Nominations may also be submitted by organizations. Nominations should include the name, address, and telephone number of the candidate. Each nomination should include a summary of the candidate's training or experience relating to BLS data specifically, or economic statistics more generally. BLS will conduct a basic background check of candidates before their appointment to the TAC. The background check will involve accessing publicly available, internet-based sources.

Authority: This notice was prepared in accordance with the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, the Secretary of Labor has determined that the Bureau of Labor Statistics Technical Advisory Committee is in the public interest in connection with the performance of duties imposed upon the Commissioner of Labor Statistics by 29 U.S.C. 1 and 2. This determination follows consultation with the Committee Management Secretariat, General Services Administration.

Signed at Washington, DC, this 10th day of September 2019.

Mark Staniorski,

*Chief, Division of Management Systems,
Bureau of Labor Statistics.*

[FR Doc. 2019–19907 Filed 9–13–19; 8:45 am]

BILLING CODE 4510–24–P

NATIONAL CREDIT UNION ADMINISTRATION

Sunshine Act Meeting

TIME AND DATE: 10:00 a.m., Thursday, September 19, 2019.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street (All visitors must use Diagonal Road Entrance) Alexandria, VA 22314–3428.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Share Insurance Fund Quarterly Report.
2. NCUA Rules and Regulations, Supervisory Committee Audits.
3. NCUA Rules and Regulations, Federal Credit Union Bylaws.
4. NCUA Rules and Regulations, Payday Alternative Loans II.

FOR FURTHER INFORMATION CONTACT:

Gerard Poliquin, Secretary of the Board,
Telephone: 703-518-6304.

Gerard Poliquin,

Secretary of the Board.

[FR Doc. 2019-20112 Filed 9-12-19; 4:15 pm]

BILLING CODE 7535-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2019-0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of September 16, 23, 30, October 7, 14, 21, 2019.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of September 16, 2019

There are no meetings scheduled for the week of September 16, 2019.

Week of September 23, 2019—Tentative

There are no meetings scheduled for the week of September 23, 2019.

Week of September 30, 2019—Tentative

There are no meetings scheduled for the week of September 30, 2019.

Week of October 7, 2019—Tentative

There are no meetings scheduled for the week of October 7, 2019.

Week of October 14, 2019—Tentative

There are no meetings scheduled for the week of October 14, 2019.

Week of October 21, 2019—Tentative

There are no meetings scheduled for the week of October 21, 2019.

CONTACT PERSON FOR MORE INFORMATION:

For more information or to verify the status of meetings, contact Denise McGovern at 301-415-0681 or via email at Denise.McGovern@nrc.gov. The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: <http://www.nrc.gov/public-involve/public-meetings/schedule.html>.

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (e.g., braille, large print), please notify Kimberly Meyer-Chambers, NRC Disability Program Manager, at 301-287-0739, by videophone at 240-428-3217, or by email at Kimberly.Meyer-Chambers@nrc.gov. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301-415-1969), or by email at Tyesha.Bush@nrc.gov.

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated at Rockville, Maryland, this 12th day of September, 2019.

For the Nuclear Regulatory Commission.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2019-20138 Filed 9-12-19; 4:15 pm]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC-2019-0085]

Information Collection: NRC Forms 366, 366A, and 366B, Licensee Event Report

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, "NRC Forms 366, 366A, and 366B, Licensee Event Report."

DATES: Submit comments by November 15, 2019. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

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

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2019-0085. Address

questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301-287-9127; email: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: T6-A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; email: Infocollects.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2019-0085 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2019-0085. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC-2019-0085 on this Website.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to pdr.resource@nrc.gov. A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Package Accession No. ML19150A230. The supporting statement and NRC Forms 366, 366A, and 366B, "Licensee Event Report," are available in ADAMS under Accession No. ML19150A303.

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One

White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; email: Infocollects.Resource@nrc.gov.

B. Submitting Comments

Please include Docket ID NRC-2019-0085 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <https://www.regulations.gov> as well as enter the comment submissions into ADAMS, and the NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* NRC Forms 366, 366A, and 366B, "Licensee Event Report" section 50.73 of title 10 of the *Code of Federal Regulations* (10 CFR).
2. *OMB approval number:* 3150-0104.
3. *Type of submission:* Revision.
4. *The form number, if applicable:* NRC Forms 366, 366A and 366B.
5. *How often the collection is required or requested:* As needed per 10 CFR 50.73, "Licensee event report system."
6. *Who will be required or asked to respond:* The holder of an operating license under 10 CFR part 50 or a combined license under 10 CFR part 52

(after the Commission has made the finding under section 52.103(g)).

7. *The estimated number of annual responses:* 350.

8. *The estimated number of annual respondents:* 98 (number of operating nuclear units in the U.S.).

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* The total estimated burden for completing Licensee Event Reports is 28,000 hours (based on 80 hours for each of 350 reports).

10. *Abstract:* Part of the NRC's function is to license and regulate the operation of commercial nuclear power plants to ensure protection of public health and safety and the environment in accordance with the Atomic Energy Act of 1954 (the Act) as amended. In order for the NRC to carry out these responsibilities, licensees must report significant events in accordance with section 50.73, so that the NRC can evaluate the events to determine what actions, if any, are warranted to ensure protection of public health and safety or the environment. Section 50.73 requires reporting on NRC Forms 366, 366A, and 366B.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the estimate of the burden of the information collection accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated at Rockville, Maryland, this 10th day of September, 2019.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2019-19897 Filed 9-13-19; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 72-20; NRC-2017-0136]

U.S. Department of Energy Idaho Operations Office; Three Mile Island Unit 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Environmental assessment and finding of no significant impact; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering the renewal of Special Nuclear Materials (SNM) License SNM-2508 for the Three Mile Island Unit 2 (TMI-2) independent spent fuel storage installation (ISFSI) located on the Idaho National Laboratory (INL) Site, formerly known as the Idaho National Environmental and Engineering Laboratory, in Scoville, Butte County, Idaho. The NRC has prepared an environmental assessment (EA) for this proposed license renewal in accordance with its regulations. Based on the EA, the NRC has concluded that a finding of no significant impact (FONSI) is appropriate, and an environmental impact statement (EIS) is not warranted. The NRC also is conducting a safety evaluation of the proposed license renewal.

DATES: The EA and FONSI referenced in this document are available on September 16, 2019.

ADDRESSES: Please refer to Docket ID NRC-2017-0136 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2017-0136. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301-287-9127; email: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION**

CONTACT section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT:

Stacey Imboden, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2462, email: Stacey.Imboden@nrc.gov.

SUPPLEMENTARY INFORMATION:**I. Introduction**

The NRC is considering a license renewal request for SNM-2508 for the TMI-2 specifically-licensed ISFSI located on the INL site in Butte County, Idaho. The applicant, the U.S. Department of Energy, Idaho Operations Office (DOE-ID), is requesting to renew license SNM-2508 for the TMI-2 ISFSI for an additional 20-year period. The current license was set to expire on March 19, 2019 but, in accordance with section 72.42 (c) of title 10 of the *Code of Federal Regulations* (10 CFR), the license will not expire until a final decision concerning the application for renewal has been made (timely renewal). If approved, DOE-ID would be able to continue to possess and store spent nuclear fuel at the TMI-2 ISFSI in accordance with the requirements in 10 CFR part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste" until March 19, 2039. However, the State of Idaho along with DOE-ID and the U.S. Department of the Navy are parties to a settlement agreement, which in part, requires that all of the TMI-2 spent fuel core debris be removed from the State of Idaho by January 1, 2035. This date falls within the 20-year license renewal period requested by DOE-ID.

The NRC staff has prepared a final EA as part of its review of this license renewal request in accordance with the requirements of 10 CFR part 51. Based on the final EA, the NRC has determined that an EIS is not required for this proposed action and a FONSI is appropriate. The NRC is also conducting a safety evaluation of the proposed license amendment pursuant to 10 CFR part 72, and the results will be documented in a separate Safety Evaluation Report (SER). If DOE-ID's request is approved, the NRC will issue the license renewal following publication of this final EA and FONSI and the SER in the **Federal Register**.

II. Final Environmental Assessment Summary

DOE-ID is requesting to renew the TMI-2 specifically-licensed ISFSI license for a 20-year period. The NRC has assessed the potential environmental impacts of the proposed

action and the no-action alternative. The results of the NRC's environmental review can be found in the final EA (ADAMS Accession No. ML19122A285). In conducting the environmental review, the NRC considered information in the license renewal application (ADAMS Package Accession No. ML19053A310) and supplemental information submitted by DOE-ID (ADAMS Accession Nos. ML17305A060 and ML17345A156); communications with the Idaho State Historic Preservation Office; the Shoshone-Bannock Tribes; the Idaho field office of the U.S. Fish and Wildlife Service; and the Idaho Department of Environmental Quality (IDEQ).

If the license renewal request is approved, DOE-ID would be able to continue to possess and store 29 dry shield canisters (DSCs) that contain 341 canisters of TMI-2 spent fuel core debris at the INL site in accordance with the requirements in 10 CFR part 72 and License SNM-2508 for an additional 20 years. DOE-ID states that no additional material will be added to the ISFSI. The estimated annual dose to the nearest potential member of the public from ISFSI activities is 0.0009 milliSieverts (mSv) [(0.09 millirem (mrem)], which is below the 0.25 mSv/yr (25 mrem/yr) limit specified in 10 CFR 72.104(a) and the 1 mSv/yr (100 mrem/yr) limit in 10 CFR 20.1301(a)(1). Furthermore, DOE-ID maintains a radiation protection program for the ISFSI in accordance with 10 CFR part 20 to ensure that radiation doses are as low as is reasonably achievable (ALARA). Accordingly, no significant radiological or non-radiological impacts are expected to result from approval of the license renewal request, and the proposed action would not significantly contribute to cumulative impacts at the ISFSI site. Additionally, there would be no disproportionately high and adverse impacts on minority and low-income populations.

In its license renewal request, DOE-ID is proposing no changes in how it manages and stores spent fuel at the TMI-2 ISFSI. Approval of the proposed action would not result in any new construction or expansion of the existing ISFSI footprint. No liquid effluents are released due to operation of the ISFSI, and all gaseous effluents from the DSCs are vented through a high-efficiency particulate air filter, resulting in doses sufficiently low that a permit for continuous monitoring is not required. No significant radiological or nonradiological impacts are expected from continued normal operations. Occupational dose estimates associated with the proposed action and continued

normal operation and maintenance of the ISFSI are expected to be at ALARA levels and within the limits of 10 CFR 20.1201. Therefore, the NRC staff has determined that pursuant to 10 CFR 51.31, preparation of an EIS is not required for the proposed action, and pursuant to 10 CFR 51.32, a FONSI is appropriate.

Furthermore, the NRC staff determined that this license renewal request does not have the potential to cause effects on historic properties, assuming those were present; therefore, in accordance with 36 CFR 800.3(a)(1), no consultation is required under Section 106 of the National Historic Preservation Act. The NRC staff, however, reached out to and informed the Idaho State Historic Preservation Officer (SHPO) (ADAMS Accession No. ML17144A373) and the Shoshone-Bannock Tribes (ADAMS Accession No. ML17146A117) via letters dated July 6, 2017 of its determination. The SHPO responded on July 27, 2017, that the proposed action would not affect any historic properties (ADAMS Accession No. ML17215A574). The NRC staff also consulted with the U.S. Fish and Wildlife Service in accordance with Section 7 of the Endangered Species Act. The draft EA was sent to the IDEQ for review in January 2019. The IDEQ had no specific comments (ADAMS Accession No. ML19050A174).

III. Finding of No Significant Impact

Based on its review of the proposed action in the EA, in accordance with the requirements in 10 CFR part 51, the NRC has concluded that the proposed action, renewal of NRC SNM-2508 for the TMI-2 ISFSI located on the INL site in Scoville, Butte County, Idaho, will not significantly affect the quality of the human environment. Therefore, the NRC has determined, pursuant to 10 CFR 51.31 that preparation of an EIS is not required for the proposed action and a FONSI is appropriate.

Dated at Rockville, Maryland, this 10th day of September, 2019.

For the Nuclear Regulatory Commission.

Kathryn M. Brock,

Acting Director, Division of Fuel Cycle Safety, Safeguards, and Environmental Review, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2019-19906 Filed 9-13-19; 8:45 am]

BILLING CODE 7590-01-P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94-409, that the Securities and Exchange Commission will hold an Open Meeting on Wednesday, September 18, 2019, at 2:00 p.m., to hear oral argument in an appeal by Alexandre S. Clug, and a cross-appeal by the Division of Enforcement, from an initial decision of an administrative law judge.

PLACE: Auditorium (L-002) at Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: On February 8, 2016, the law judge found that (i) Clug and Aurum Mining, LLC violated Section 17(a) of the Securities Act of 1933 and Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder by making material misrepresentations and omissions to investors; (ii) PanAm Terra, Inc. violated Securities Act Section 17(a)(2) by making material misrepresentations and omissions to investors; (iii) Clug and The Corsair Group violated Exchange Act Section 15(a)(1) by acting as unregistered brokers; and (iv) Clug aided, abetted, and caused a violation by Michael W. Crow of Exchange Act Section 15(b)(6)(B). The law judge also found that Crow was not a de facto executive officer of PanAm, and therefore that PanAm was not primarily liable or Clug secondarily liable for violating Securities Act Section 17(a), Exchange Act Sections 10(b) and 13(a), and Exchange Act Rules 10b-5, 12b-20, 13a-1, and 13a-13, and that Clug did not violate Exchange Act Rule 13a-14(a) by failing to disclose Crow's role at PanAm in its periodic reports.

The law judge ordered that Clug cease-and-desist from further violations, pay disgorgement plus prejudgment interest, and be barred from the securities industry and from participating in penny stock offerings. The law judge did not sanction Aurum, PanAm, or Corsair.

Clug appealed the law judge's findings of fact and conclusions of law as to his violations and sanctions. The Division cross-appealed the findings related to Crow's role at PanAm and the sanctions for Clug, Aurum, PanAm, and Corsair. The issues likely to be considered at oral argument include whether Clug, Aurum, PanAm, and

Corsair committed the above violations and what, if any, sanctions are appropriate.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551-5400.

Dated: September 11, 2019.

Vanessa A. Countryman,
Secretary.

[FR Doc. 2019-20038 Filed 9-12-19; 11:15 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-86916; File No. SR-CBOE-2019-051]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Rules Regarding How Complex Orders Are Processed Through the Automated Improvement Mechanism and To Move Those Rules From the Currently Effective Rulebook to the Shell Structure for the Exchange's Rulebook That Will Become Effective Upon the Migration of the Exchange's Trading Platform to the Same System Used by the Cboe Affiliated Exchanges

September 10, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on August 28, 2019, Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal pursuant to Section 19(b)(3)(A)(iii) of the Act³ and Rule 19b-4(f)(6) thereunder.⁴ 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 the Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") proposes to amend its Rules regarding how complex orders are processed through the Automated Improvement Mechanism ("C-AIM" or

"C-AIM Auction"), and move those Rules from the currently effective Rulebook ("current Rulebook") to the shell structure for the Exchange's Rulebook that will become effective upon the migration of the Exchange's trading platform to the same system used by the Cboe Affiliated Exchanges (as defined below) ("shell Rulebook"). The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In 2016, the Exchange's parent company, Cboe Global Markets, Inc. (formerly named CBOE Holdings, Inc.) ("Cboe Global"), which is also the parent company of Cboe C2 Exchange, Inc. ("C2"), acquired Cboe EDGA Exchange, Inc. ("EDGA"), Cboe EDGX Exchange, Inc. ("EDGX" or "EDGX Options"), Cboe BZX Exchange, Inc. ("BZX" or "BZX Options"), and Cboe BYX Exchange, Inc. ("BYX" and, together with Cboe Options, C2, EDGX, EDGA, and BZX, the "Cboe Affiliated Exchanges"). The Cboe Affiliated Exchanges are working to align certain system functionality, retaining only intended differences between the Cboe Affiliated Exchanges, in the context of a technology migration. Cboe Options intends to migrate its trading platform to the same system used by the Cboe Affiliated Exchanges, which the Exchange expects to complete on October 7, 2019. Cboe Options believes offering similar functionality to the

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴ 17 CFR 240.19b-4(f)(6).

extent practicable will reduce potential confusion for market participants.

In connection with this technology migration, the Exchange has a shell Rulebook that resides alongside its current Rulebook, which shell Rulebook will contain the Rules that will be in place upon completion of the Cboe Options technology migration. The Exchange proposes to add the provisions of its Rules regarding C-AIM Auctions, as proposed to be modified in this rule filing, to Rule 5.38 in the shell Rulebook.⁵

The proposed rule change moves the provisions regarding AIM Auctions for complex orders from current Interpretations and Policies .07 and .08(b)⁶ to proposed Rule 5.38, and provides additional detail to the Rules, as well as makes certain additional changes. Current Interpretation and Policy .07 states complex orders may be executed through an AIM Auction at a net debit or net credit price provided the eligibility requirements in current Rule 6.74A(a) are satisfied and the Agency Order is eligible for an AIM Auction considering its complex order type, order origin code (*i.e.*, non-broker-dealer public customer, broker-dealers that are not Market-Makers or specialists on an options exchange, and/or Market-Makers or specialists on an options exchange), class, and marketability as determined by the Exchange. Order allocation is the same as in current Rule 6.74A(b)(3), provided that complex order priority rules applicable to bids and offers in the individual series legs of a complex order contained in current Rule 6.53C(d) or Interpretation and Policy .06, as applicable, will continue to apply. Current Rule 6.74A, Interpretation and Policy .08(b) states that complex orders may be eligible for AIM customer-to-customer immediate crosses in the same manner as simple orders, except the condition that requires the execution price of those crosses to not be through the NBBO will not apply, and instead the execution price may not be through the BBO.

The Exchange believes it will provide more clarity to the Rules to have a separate rule regarding how AIM Auctions apply to complex orders (“C-AIM Auctions”), and thus proposes to add Rule 5.38 to the shell Rulebook. As they are today, complex orders will continue to be processed and executed in a C-AIM Auction in a substantially similar manner as simple orders are

processed and executed in an AIM Auction pursuant to Rule 5.37 in the shell Rulebook,⁷ and therefore proposed Rule 5.38 is substantially similar to Rule 5.37 in the shell Rulebook.⁸

The proposed rule change codifies in the proposed introductory paragraph⁹ that the Initiating Order may consist of one or more solicited orders. This accommodates multiple contra-parties and increases the opportunities for customer orders to be submitted into a C-AIM Auction with the potential for price improvement, since the Initiating Order must stop the full size of the Agency Order. This has no impact on the execution of the Agency Order, which may already trade against multiple contra-parties depending on the final auction price, as set forth in proposed paragraph (e) (and current Rule 6.74A(b)(3) and Interpretation and Policy .07). This proposed change is consistent with the Exchange’s current interpretation of current Rule 6.74A, and the proposed rule change clarifies this in the Rule.¹⁰

The proposed rule change deletes the restriction that a solicited order cannot be for the account of any Market-Maker appointed in the class. Current Rule 6.74A, Interpretation and Policy .04, which applies to AIM Auctions of complex orders), imposes this restriction.¹¹ With respect to the simple markets, appointed Market Makers have a variety of obligations related to providing liquidity and making

competitive markets in their appointed classes. Therefore, prohibiting Market-Makers from being solicited in a simple AIM Auction may encourage those Market-Makers to provide liquidity in that auction to provide liquidity through responses, as well as quotes on the Book that may have the opportunity to execute against the Agency Order. Because Market-Makers have no obligations to provide liquidity to complex markets (and there is no quoting functionality available in the complex order book (“COB”)), appointed Market-Makers are on equal footing with all other market participants with respect to C-AIM Auctions. Permitting Market-Makers to be solicited provides all market participants with the opportunity to provide liquidity to execute against Agency Orders in C-AIM Auctions in the same manner (both through solicitation, responses, and interest resting on the COB).¹² EDGX Options Rule 21.22 similar does not restrict appointed Market-Makers from being solicited to participate on the contra-side of C-AIM Auctions.

The proposed introductory paragraph for Rule 5.38 is the same as the corresponding paragraph for simple AIM (Rule 5.37 in the shell Rulebook), except [sic] introductory paragraph for simple AIM Auctions does not permit the Initiating Order to be comprised of orders for the account of an appointed Market-Maker, and it refers to NBBO rather than SBBO. There is no NBBO for complex orders, as complex orders may be executed without consideration of any prices for the complex strategy that might be available on other exchanges trading the same complex strategy.¹³

Proposed Rule 5.38(a) sets forth eligibility requirements for a C-AIM Auction. Proposed Rule 5.38(a)(5) states the Trading Permit Holder that electronically submits an order into an AIM Auction (the “Initiating TPH”) may not designate an Agency Order or Initiating Order as Post Only. A Post Only complex order is a complex order the System ranks and executes pursuant to Rule 5.33 in the shell Rulebook,¹⁴

¹² As further discussed below, the Exchange will no longer restrict Users that may submit responses to C-AIM Auctions.

¹³ See current Rule 6.53C (which the Exchange intends to move to Rule 5.33 in the shell Rulebook). Additionally, executions of legs of complex orders are exceptions to the prohibition of trade-throughs. See Rule 6.81(b)(8) in the current Rulebook (Rule 6.57(b)(8) in the shell Rulebook).

¹⁴ The Exchange intends to move the provisions regarding electronic processing of complex orders from Rule 6.53C of the current Rulebook to Rule 5.33 in the shell Rulebook. The Exchange does not currently offer Post Only functionality, but will following the technology migration. See Rule 5.6(c)

⁵ Proposed Rule 5.38 is substantially the same as EDGX Options Rule 21.22, except as otherwise described below.

⁶ The Exchange proposed to delete Rule 6.74A, Interpretation and Policy .07 from current Rulebook in SR-CBOE-2019-045 (filed August 27, 2019).

⁷ See current Rule 6.74A, Interpretation and Policy .07 (“complex orders may be executed through the [AIM] Auction at a net debit or net credit price” with certain exceptions”); see also Securities Exchange Act Release No. 57610 (April 3, 2008), 73 FR 19535 (April 10, 2008) (SR-CBOE-2008-14) (which approved current Rule 6.74A, Interpretation and Policy .07 and acknowledged that, except as set forth in that Interpretation and Policy, all other aspects of the AIM Auction would continue to apply unchanged).

⁸ The Exchange recently proposed certain amendments to the simple AIM Auction, many of which the Exchange similar proposes to apply to C-AIM Auctions. See SR-CBOE-2019-048 (filed August 27, 2019). The Exchange notes it proposed to delete all of current Rule 6.74A in that rule filing, and thus the proposed rule change merely adds all provisions that are applicable to C-AIM Auctions (as proposed to be amended) to the shell Rulebook.

⁹ The proposed rule change also adds to the proposed introductory paragraph that for purposes of proposed Rule 5.38, the term “SBBO” means the synthetic best bid or offer on the Exchange at the particular point in time applicable to the reference. This is merely an addition of terminology used throughout the Rule, but has no impact on functionality.

¹⁰ See Cboe Options Regulatory Circular RG17-074 (May 19, 2017); see also EDGX Rule 21.19; and NASDAQ ISE, LLC (“ISE”) Rule 723(b); see also Rule 5.37, introductory paragraph in the shell Rulebook; and EDGX Options Rule 21.22, introductory paragraph.

¹¹ This restriction exists for simple AIM Auctions. See Rule 5.37, introductory paragraph in the shell Rulebook.

subjects to the Price Adjust process pursuant to Rule 5.32 in the shell Rulebook, or cancels or rejects (including if it is not subject to the Price Adjust process and locks or crosses a Protected Quotation of another exchange), as applicable (in accordance with User instructions), except the order or quote may not remove liquidity from the Book or route away to another Exchange. The Exchange does not currently offer Post Only order functionality, but will as of the technology migration.¹⁵ The Exchange believes it is appropriate to not permit the Agency or Initiating Order to be designated as Post Only, as the purpose of a Post Only order is to not execute upon entry and instead rest in the COB, while the purpose of a C-AIM Auction is to receive an execution following the Auction but prior to entering the COB. Proposed Rule 5.38(a)(6) states the Initiating TPH may only submit an Agency Order to a C-AIM Auction after the COB opens. This is consistent with current functionality, as executions cannot occur prior to the opening of trading. The proposed rule change clarifies this in the Rule.

The proposed rule change moves the various other C-AIM Auction eligibility requirements to proposed paragraph (a) and makes nonsubstantive changes:

- The requirement that an Agency Order be in a class of options the Exchange designates as eligible for C-AIM Auctions moves from current Interpretation and Policy .07 to proposed subparagraph (a)(1).¹⁶

in the shell Rulebook (which describes Post Only functionality for simple orders). The Exchange intends to adopt a similar definition of Post Only for complex orders, which will be virtually identical to the definition of Post Only complex orders in the rules of Cboe Affiliated Exchanges. See C2 Rule 6.13(b)(5) and EDGX Options Rule 21.20(b) (which define a Post Only complex order as a complex order the System ranks and executes pursuant to C2 Rule 6.1e [sic] or EDGX Options Rule 21.20, respectively, or cancels or rejects, as applicable (in accordance with the User's instructions), except the order may not remove liquidity from the COB or the Simple Book. The System cancels or rejects a Post Only market complex order unless it is subject to each exchange's drill-through protection.

¹⁵ See Cboe Options Rule 5.6(c) in the shell Rulebook; see also Securities Exchange Act Release No. 86173 (June 20, 2019), 84 FR 30267 (June 26, 2019) (SR-CBOE-2019-027) (which filing added the Post Only order instruction to the shell Rulebook).

¹⁶ The proposed rule change deletes the provisions that the Agency Order be an order type, have a Capacity (currently referred to as origin code), or meet marketability criteria determined by the Exchange, as the current and proposed rule explicitly state any applicable eligibility parameters. Additionally, the Exchange will announce all determinations it may make with respect to a C-AIM Auction pursuant to Rule 1.5 in the shell Rulebook, and therefore current Interpretation and Policy .05 (and other provisions

- The requirement that the Initiating TPH mark an Agency Order for AIM processing moves from current subparagraph (b)(1)(A) to proposed subparagraph (a)(2).

- The provision that there is no minimum size for Agency Orders moves from current Interpretation and Policy .03 to proposed subparagraph (a)(3). Additionally, the requirement that the Initiating Order be for the same size as the Agency Order moves from current subparagraphs (a)(2) and (a)(3) to proposed subparagraph (a)(3).

- The provision regarding the minimum increment for the Agency Order and Initiating Order price moves from current subparagraph (a)(3) to proposed subparagraph (a)(4). The proposed rule change makes no changes to the permissible minimum increments for C-AIM Auctions and merely moves it to a new provision in the shell Rulebook.

The proposed rule change also explicitly states that all of the eligibility requirements in proposed paragraph (a) must be met for a C-AIM Auction to be initiated, and that the System rejects or cancels both an Agency Order and Initiating Order submitted to an AIM Auction that do not meet the conditions in proposed paragraph (a).

Proposed Rule 5.38(a) is the same as the corresponding paragraph for simple AIM (Rule 5.37(a)), except the proposed rule change does not provide that an Initiating TPH may not submit an Agency Order if the NBBO is crossed (unless the Agency Order is an AIM ISO or Sweep and AIM). As noted above, there is no NBBO for complex orders, and the legs of complex orders are not subject to the restriction on NBBO trade-throughs. Additionally, the proposed rule change references the opening of the complex order book ("COB") rather than the market open, as the opening of the COB is when complex orders may begin trading.

Proposed Rule 5.38(b) sets forth the requirements for the stop price of the Agency Order. It states the Initiating Order must stop the entire Agency Order at a price that satisfies the following:

- If the Agency Order is to buy (sell) and (a) the applicable side of the BBO on any component of the complex strategy represents a Priority Customer order on the Simple Book, the stop price must be at least one minimum increment better than the SBB (SBO); or (b) the applicable side of the BBO on each component of the complex strategy represents a non-Priority Customer

regarding how the Exchange will announce these determinations) is no longer necessary.

order or quote on the Simple Book, the stop price must be at or better than the SBB (SBO). This ensures the execution price of the Agency Order will improve the SBBO if there is a Priority Customer order in any of the legs on the Simple Book. The proposed rule change protects Priority Customers in any of the component legs of the Agency Order in the Simple Book. By permitting a Priority Customer Agency Order to trade at the SBBO if there is a resting non-Priority Customer order in the Book, the proposed rule change also protects Priority Customer orders submitted into a C-AIM Auction. The Exchange believes the proposed rule change is consistent with general customer priority principles.¹⁷

- If the Agency Order is to buy (sell) and a buy (sell) complex order rests on the COB, the stop price must be at least one minimum increment better than the bid (offer) of the resting complex order, unless the Agency Order is a Priority Customer order and the resting order is a non-Priority Customer order, in which case the stop price must be at or better than the bid (offer) of the resting complex order. This ensures the execution price of the Agency Order will improve the price of any resting Priority Customer complex orders on the COB, and that the execution price of a Priority Customer Agency Order will not be inferior to the price of any resting non-Priority Customer complex orders on the COB.¹⁸ Current Rule 6.74A(b)(3)(I) states if the final auction price locks a Priority Customer order in the Book (which would be the COB for purposes of complex orders) on the same side of the market as the Agency Order, then, unless there is sufficient size in the Auction responses to execute both the Agency Order and the booked Priority Customer order (in which case they will both execute at the final auction price), the Agency Order will execute against the auction responses at one minimum increment worse than the final auction price against the auction participants that submitted the final auction price and any balance will trade against the priority customer order in

¹⁷ General principles of customer priority ensure the execution price of complex orders will not be executed at prices inferior to the SBBO or at a price equal to the SBBO when there is a Priority Customer at the BBO for any component.

¹⁸ This corresponds to the same-side simple order check for AIM, which requires the Agency Order to improve the price of a resting Priority Customer order on the Simple Book, or a non-Priority Customer order or quote on the Simple Book unless the Agency Order is for a Priority Customer and the resting order is not a Priority Customer, in which case the stop price must be at or better than the Exchange best bid (offer). See Rule 5.37(b)(2) in the shell Rulebook.

the book at the order's limit price. The proposed rule change protects Priority Customers on the same side of the COB as the current rule does, except it does so by applying a check at the initiation of a C-AIM Auction rather than at the conclusion of a C-AIM Auction. By permitting a Priority Customer Agency Order to trade at the same price as a resting non-Priority Customer order, the proposed rule change also protects Priority Customer orders submitted into a C-AIM Auction. Additionally, application of this check at the initiation of a C-AIM Auction may result in the Agency Order executing at a better price, since the stop price must improve any same-side complex orders (with the exception of a Priority Customer Agency Order and a resting non-Priority Customer order described above), as under the current Rule, the Agency Order may execute at one minimum increment worse. The proposed rule change is consistent with general customer priority principles.

- If the Agency Order is to buy (sell) and (a) the BBO of any component of the complex strategy represents a Priority Customer order on the Simple Book, the stop price must be at least one minimum increment better than the SBO (SBB), or (b) the BBO of each component of the complex strategy represents a non-Priority Customer order on the Simple Book, the stop price must be at or better than the SBO (SBB). This ensures the execution price of the Agency Order will improve the price of the opposite side of the SBBO if there is a Priority Customer order on any leg, and not be through the opposite side of the SBBO. While the stop price may cross the opposite side best-priced complex order resting on the opposite side of the COB, as noted below, any complex interest at a better price than the stop price will trade ahead of the Initiating Order. Pursuant to proposed paragraph (e), any contra-side interest available at better prices than the stop price at the conclusion of a C-AIM Auction will execute against the Agency Order ahead of the Initiating Order. Therefore, the Agency Order will execute at the best prices available at the conclusion of the C-AIM Auction, even if the stop price was inferior to those prices. Simple AIM Auctions may similarly start at prices inferior to the NBBO for the series in certain instances.¹⁹

¹⁹ Simple AIM has no price checks for orders on the opposite side of the Agency Order. See Rule 5.37(b) in the shell Rulebook. The proposed rule change adopts price checks for simple orders that constitute the SBBO on the opposite side of the Agency Order to ensure that the Agency Order does not execute at a price through the opposite side

- The Initiating TPH must specify (a) a single price at which it seeks to execute the Agency Order against the Initiating Order (a "single-price submission"), including whether it elects to have last priority in allocation (as described below), or (b) an initial stop price and instruction to automatically match the price and size of all C-AIM responses and other trading interest ("auto-match") up to a designated limit price or at all prices that improve the stop price. The proposed rule change moves this provision from current subparagraph (b)(1)(A) to proposed subparagraph (b)(3). It is also the same as the corresponding simple AIM provision.²⁰ The proposed rule change also explicitly states that all of the conditions in proposed paragraph (b) must be met for a C-AIM Auction to be initiated, and that the System rejects or cancels both an Agency Order and Initiating Order submitted to a C-AIM Auction that do not meet the conditions in proposed paragraph (b).

Proposed paragraph (c) describes the C-AIM Auction process. Currently, only one C-AIM Auction may be ongoing at any given time in a series, and C-AIM Auctions in the same series may not queue or overlap in any manner.²¹ The Exchange proposes to permit concurrent C-AIM Auctions in the same complex strategies. Pursuant to proposed Rule 5.38(c)(1), with respect to Agency Orders for which the smallest leg is less than 50 standard option contracts (or 500 mini-option contracts), only one C-AIM Auction may be ongoing at any given time in a complex strategy, and C-AIM Auctions in the same complex strategy may not queue or overlap in any manner. Therefore, the proposed rule change has no impact on these smaller Agency Orders. One or more C-AIM Auctions in the same complex strategy for Agency Orders for which the smallest leg is 50 standard option contracts (or 500 mini-option contracts) or more may occur at the same time. C-AIM Auctions in different complex strategies may be ongoing at any given time, even if the complex strategies have

SBBO to protect orders (including Priority Customer orders) resting in the Simple Book. While there is no complex AIM sweep or complex sweep and AIM order for C-AIM, because complex orders do not route (and there is no applicable NBBO), permitting the stop price to cross the opposite side of the COB is consistent with those order types in simple AIM, which permit the stop price to be inferior to the Initial NBBO. See Rule 5.37(b)(3) in the shell Rulebook. The execution at the conclusion of a C-AIM Auction will essentially "sweep" better-priced contra-side complex interest that is available on the Exchange.

²⁰ See Rule 5.37(b)(4) in the shell Rulebook.

²¹ See current Rule 6.74A(b).

overlapping components. A C-AIM Auction may be ongoing at the same time as an AIM Auction in any component of the complex strategy.

To the extent there is more than one C-AIM Auction in a complex strategy underway at a time, the C-AIM Auctions conclude sequentially based on the exact time each C-AIM Auction commenced, unless terminated early pursuant to proposed Rule 5.38(d). In the event there are multiple C-AIM Auctions underway that are each terminated early pursuant to proposed paragraph (d), the System processes the C-AIM Auctions sequentially based on the exact time each C-AIM Auction commenced. If the System receives a simple order that causes an AIM and C-AIM (or multiple AIM and/or C-AIM) Auctions to conclude pursuant to proposed Rules 5.37(d) and 5.38(d), the System first processes AIM Auctions (in price-time priority) and then processes C-AIM Auctions (in price-time priority). At the time each C-AIM Auction concludes, the System allocates the Agency Order pursuant to proposed paragraph (e) and takes into account all C-AIM Auction responses and unrelated orders and quotes in place at the exact time of conclusion.²²

The Exchange believes it is appropriate to permit concurrent C-AIM Auctions in the same complex strategy (for Agency Orders for which the smallest leg is for 50 or more contracts). Different complex strategies are essentially different products, as orders in those strategies cannot interact, just as orders in different series or classes cannot interact. Similarly, while it is possible for a complex order to leg into the Simple Book, a complex order may only execute against simple orders if there is interest in each component in the appropriate ratio for the complex strategy. A simple order in one component of a complex strategy cannot on its own interact with a complex order in that complex strategy. Therefore, the Exchange believes it is appropriate to permit concurrent AIM and C-AIM Auctions that share a component. As proposed, C-AIM Auctions will ensure that Agency Orders execute at prices that protect

²² See proposed Rule 5.38(c)(1), which is the same as the corresponding proposed paragraph for simple AIM (see Rule 5.37(c)(1) in the shell Rulebook), except the proposed change adds how the System will handle ongoing auctions that include an overlapping component (whether that component is the subject of an ongoing simple AIM Auction or part of a complex strategy for which a different C-AIM Auction is ongoing) and adds that whether concurrent C-AIM Auctions (subject to the same minimum size restriction as simple orders) in the same complex strategy may occur is based on the size of the smallest leg of the Agency Order.

Priority Customer orders in the Simple Book and that are not inferior to the SBBO at the conclusion of the C-AIM Auction, even when there are concurrent simple and complex auctions occurring. The proposed rule change sets forth how any AIM auctions with overlapping components will conclude if terminated due to the same event.

The Exchange notes it is currently possible for auctions in a component leg and a complex strategy containing that component (such as a simple AIM Auction in the component and a complex order auction ("COA") in the complex strategy that contains that component) to occur concurrently, and at the end of each auction, it is possible for interest resting in the Simple Book to trade against the complex order subject to the COA. While these auctions may be occurring at the same time, they will be processed in the order in which they are terminated (similar to how the System will process auctions as proposed above). In other words, suppose today there is an AIM Auction in a series and a COA in a complex strategy for which one of the components is the same series both occurring, which began and will terminate in that order, and each of which last 100 milliseconds. While it is possible for both auctions to terminate nearly simultaneously, the System will still process them in the order in which they terminate. When the AIM Auction terminates, the System will process it in accordance with current Rule 6.74A (Rule 5.37 in the shell Rulebook), and the auctioned order may trade against any resting interest (in addition to the contra-side order and responses submitted to that AIM Auction, which may only trade against the order auctioned in that AIM current Rule 6.74A (Rule 5.37 in the shell Rulebook)). The System will then process the COA Auction when it terminates, and the auctioned order may trade against any resting interest, including any simple interest that did not execute against the AIM order (in addition to the contra-side order and responses submitted to that COA Auction, which may only trade against the order auctioned in that COA), pursuant to current Rule 6.53C.²³

The proposed rule change moves and makes nonsubstantive changes to other provisions regarding the C-AIM Auction process to proposed paragraph (c):

- The proposed rule change moves the provision regarding the C-AIM

Auction notification message (currently called a request for responses ("RFR")) from current subparagraph (b)(1)(B) to proposed subparagraph (c)(2). The proposed provision specifies that the message will detail the side, size, Auction ID, and complex strategy of the Agency Order to all Users that elect to receive C-AIM Auction notification messages. This is consistent with the current RFR that is disseminated. The current rule states that the RFR states the side and size of the Agency Order; the proposed rule change adds details regarding other information that is included in the notification messages. The Exchange believes not certain information about the Agency Order (such as the stop price and Capacity) encourages market participants to submit responses with their best possible prices, which may result in more price improvement for the Agency Order. The proposed rule change also adds that C-AIM Auction notification messages are not included in OPRA, which is also consistent with current functionality.

- The proposed rule change moves the provision regarding the length of the C-AIM Auction period from current subparagraph (b)(1)(C) to proposed subparagraph (c)(3). The proposed rule change makes no changes to the current range of permitted lengths of C-AIM Auction periods.

- The proposed rule change moves the provision that prohibits an Initiating TPH from modifying or cancelling an Agency Order or Initiating Order after submission to a C-AIM Auction from current subparagraph (b)(1)(A) to proposed subparagraph (c)(4).

The proposed rule change also moves all provisions regarding C-AIM Auction responses into proposed subparagraph (c)(5), as well as makes certain changes described below, as well as nonsubstantive changes:

- The proposed rule change moves the provision regarding which market participants may respond to C-AIM Auctions from current subparagraphs (b)(1)(D) and (E) to proposed subparagraph (c)(5). Currently, only Market-Makers with an appointment in the applicable class and Trading Permit Holder ("TPHs") representing orders as agent at the top of the Book may respond to C-AIM Auctions.²⁴ The

²⁴ See current Rule 6.74A(b)(1)(D) and (E) (pursuant to current Interpretation and Policy .07, these provisions apply to AIM Auctions of complex orders); and Rule 5.37(c)(5) in the shell Rulebook; see also *supra* note 7 and Choe Options Regulatory Circular RG17-145 (October 17, 2017) (which Regulatory Circular states that the restrictions on which market participants may respond to AIM Auctions applies to both auctions of simple orders and complex orders).

Exchange proposes to permit all Users (other than the Initiating TPH (the response cannot have the same EFID as the Initiating Order))²⁵ to respond to C-AIM Auctions. By permitting additional participants to submit responses to C-AIM Auctions, the Exchange believes this may provide the opportunity for additional liquidity in these auctions, which could lead to additional price improvement opportunities. EDGX Options similarly permits all Users to respond to C-AIM Auctions.²⁶

- The proposed rule change moves provisions regarding what must be specified in the responses (including price, size, side, and Auction ID) from current subparagraphs (b)(1)(D) and (E) to proposed subparagraph (c)(5).

- The current rule specifies that responses must specify prices and sizes; the proposed rule change adds responses must also specify side and an Auction ID. The proposed rule change adds that a C-AIM response may only participate in the C-AIM Auction with the Auction ID specified in the response. This is consistent with current functionality.²⁷ The Exchange proposes to include this language given the above proposal that permits concurrent C-AIM Auctions in the same series for larger Agency Orders.

- The proposed rule change moves the provision regarding the permissible minimum increment for C-AIM responses from current subparagraph (b)(1)(G) to proposed subparagraph (c)(5)(A), but makes no substantive changes.

- Proposed subparagraph (c)(5)(B) states that C-AIM buy (sell) responses are capped at the following prices that exist at the conclusion of the C-AIM Auction: (i) the better of the SBO (SBB)

²⁵ As further discussed below, the Initiating Order may receive an entitlement of 40% or 50% of the Agency Order. The Exchange believes it is appropriate to not permit the Initiating TPH to also submit responses in order to try to trade against a larger percentage of the Agency Order. This is consistent with proposed allocation rules, pursuant to which the Initiating Order may only receive more than 40% or 50%, as applicable, of the Agency Order if there are remaining contracts after all other interest has executed. See proposed Rule 5.38(e)(1).

²⁶ See EDGX Options Rule 21.22(c)(5).

²⁷ Current subparagraph (b)(3)(K) permits an unexecuted balance of a response to an AIM Auction of a complex order after the Agency Order has been executed and the balance to trade against any unrelated order(s) that cause the AIM Auction of a complex order to conclude. The proposed rule change deletes that provision given the proposed rule change to permit concurrent auctions, as described above, and thus the requirement that responses may only trade with an Agency Order in the C-AIM Auction into which the C-AIM response was submitted. If a responder wishes to execute interest against any orders that caused a C-AIM Auction to conclude and that are resting in the Book, that responder may separately submit an order to the Exchange.

²³ The Exchange will similarly permit concurrent simple AIM Auctions upon the technology migration. See Rule 5.37(c)(1) in the shell Rulebook.

or the offer (bid) of a resting complex order at the top of the COB; or (ii) one minimum increment lower (higher) than the better of the SBO (SBB) or the offer (bid) of a resting complex order at the top of the COB if the BBO of any component of the complex strategy or the resting complex order, respectively, is a Priority Customer order. The System executes these C-AIM responses, if possible, at the most aggressive permissible price not outside the SBBO at the conclusion of the C-AIM Auction or price of the resting complex order. This will ensure the execution price is at or better than the SBBO or prices of resting complex orders at the end of the C-AIM Auction, which the stop price must be at or better than (and must be better than if represented by a Priority Customer order) as set forth in proposed Rule 5.38(e).²⁸ This is similar to current subparagraph (b)(1)(E), which does not permit responses to cross the opposite side of the Exchange's disseminated quote that exists at the conclusion of the Auction.²⁹

- Proposed subparagraph (c)(5)(C) states a User may submit multiple C-AIM responses at the same or multiple prices to a C-AIM Auction. This is consistent with current functionality. Current Rule 6.74A contains no restriction on how many responses a User may submit; the proposed rule change merely makes this explicit in the Rules. The proposed rule change also states for purposes of a C-AIM Auction, the System aggregates all of a User's complex orders on the COB and C-AIM responses for the same EFID at the same price. This (combined with the proposed size cap) will prevent a User from submitting multiple orders or responses at the same price to obtain a larger pro-rata share of the Agency Order.³⁰

- Proposed subparagraph (c)(5)(D) states the System caps the size of a C-AIM response, or the aggregate size of a User's complex orders on the COB and C-AIM responses for the same EFID at

the same price, at the size of the Agency Order (*i.e.*, the System ignores size in excess of the size of the Agency Order when processing the C-AIM Auction). This is consistent with current subparagraph (b)(1)(H), except the proposed rule change caps the aggregate size of a User's interest at the same price, rather than the size of an individual response. The Exchange believes this is reasonable to prevent a User from submitting an order, quote, or response with an extremely large size in order to obtain a larger pro-rata share of the Agency Order.³¹

- Proposed subparagraph (c)(5)(E) states C-AIM responses must be on the opposite side of the market as the Agency Order, and the System rejects an AIM response on the same side of the market as the Agency Order. This is consistent with current functionality, and the proposed rule change merely adds this detail to the rules. Additionally, the Exchange believes this is reasonable given that the purpose of a C-AIM response is to trade against the Agency Order in the C-AIM Auction into which the C-AIM response was submitted.³²

- Proposed subparagraph (c)(5)(F) states C-AIM responses may be designated with the match trade prevention ("MTP") modifier of MTP Cancel Newest, but no other MTP modifiers, and the System rejects a C-AIM response with any other MTP modifier.³³ An incoming order marked with MTP Cancel Newest will not execute against opposite side interest marked with any MTP modifier originating from the same Unique Identifier, and the incoming order (the C-AIM response in this case) will be cancelled back to the originating User. If an Agency Order and response have the same Unique Identifier and an MTP modifier, the System will cancel the response and permit the Agency Order to execute against other interest. This is consistent with the prohibition on the Agency Order being cancelled after it is submitted.³⁴

²⁸ The proposed rule change also does not specify that C-AIM responses may not be designated as FOK (as Rule 5.37 in the shell Rulebook does). The Exchange does intend to permit complex orders to be designated as FOK, and thus does not need to specify for complex responses that Time-in-Force will not be available.

²⁹ This is also consistent with a similar requirement for responses to a simple AIM Auction, except the proposed rule change references the SBBO and orders on the COB rather than the BBO and prices of orders on the Simple Book. See Rule 5.37(c)(5)(B) in the shell Rulebook.

³⁰ This is similar to the corresponding provision for simple AIM Auctions, except that provision also aggregates quotes (there is not quoting functionality available for complex orders), so it is not included in the C-AIM provision. See Rule 5.37(c)(5)(C) in the shell Rulebook.

³¹ This is similar to the corresponding provision for simple AIM Auctions, except that provision also aggregates quotes (there is not quoting functionality available for complex orders), so it is not included in the C-AIM provision. See Rule 5.37(c)(5)(D) in the shell Rulebook.

³² This is similar to the corresponding provision for simple AIM Auctions. See Rule 5.37(c)(5)(E) in the shell Rulebook.

³³ See Rule 5.6(c) in the shell Rulebook for definitions of the various types of MTP Modifiers that will be available on the Exchange as of the System migration. The Exchange does not currently have any equivalent to an MTP modifier that may be applied to orders or auction responses.

³⁴ This is similar to the corresponding provision for simple AIM Auctions. See Rule 5.37(c)(5)(F) in the shell Rulebook.

- Proposed subparagraph (c)(5)(G) states C-AIM responses may not be designated as immediate-or-cancel ("IOC") and the System rejects a C-AIM response designated as IOC.³⁵ This is consistent with the purpose of a C-AIM response, which is to potentially execute against an Agency Order at the conclusion of a C-AIM Auction (and thus not immediately upon entry, as required by the time-in-force of IOC).³⁶

- The provision that states C-AIM responses are not visible to C-AIM Auction participants or disseminated to OPRA moves from current subparagraph (b)(1)(F) to proposed subparagraph (c)(5)(H).³⁷

- The provision that states C-AIM responses may be cancelled moves from current subparagraph (b)(1)(I) to proposed subparagraph (c)(5)(I). The proposed rule change also clarifies that C-AIM responses may be modified (which is consistent with current functionality and merely clarified in the rules).³⁸

Pursuant to proposed Rule 5.38(d), a C-AIM Auction concludes at the earliest to occur of the following times:

- The end of the C-AIM Auction period;
- upon receipt by the System of an unrelated non-Priority Customer complex order on the same side as the Agency Order that would post to the COB at a price better than the stop price;
- upon receipt by the System of an unrelated Priority Customer complex order on the same side as the Agency Order that would post to the COB at a price equal to or better than the stop price;
- upon receipt by the System of an unrelated non-Priority Customer order or quote that would post to the Simple Book and cause the SBBO on the same side as the Agency Order to be better than the stop price;
- upon receipt by the System of a Priority Customer order in any

³⁵ See Rule 5.6(d) in the shell Rulebook. Current C-AIM response functionality does not permit a User to apply this order instruction to C-AIM responses.

³⁶ This is similar to the corresponding provision for simple AIM Auctions, except that provision also prohibits Users from designated an AIM response as fill-or-kill ("FOK"), which time-in-force will not be available for complex orders, and thus the proposed rule change does not include it in the C-AIM Rule. See Rule 5.37(c)(5)(G) in the shell Rulebook.

³⁷ This is similar to the corresponding provision for simple AIM Auctions. See Rule 5.37(c)(5)(H) in the shell Rulebook.

³⁸ This is similar to the corresponding provision for simple AIM Auctions. See Rule 5.37(c)(5)(I) in the shell Rulebook. Proposed subparagraph (e)(6) states the System will cancel or reject any unexecuted C-AIM responses (or unexecuted portions) at the conclusion of the C-AIM Auction.

component of the complex strategy that would post to the Simple Book and cause the SBBO on the same side as the Agency Order to be equal to or better than the stop price;

- upon receipt by the System of a simple non-Priority Customer order that would cause the SBBO on the opposite side of the Agency Order to be better than the stop price, or a Priority Customer order that would cause the SBBO on the opposite side of the Agency Order to be equal to or better than the stop price;

- upon receipt by the System of an order that would cause the SBBO to be a price not permissible under the Limit Up-Limit Down Plan or Regulation SHO, provided, however, that in such instance, the C-AIM Auction concludes without execution;

- the market close; and
- any time the Exchange halts trading in the complex strategy or any component of the complex strategy, provided, however, that in such instance, the C-AIM Auction concludes without execution.

The proposed events that would cause a C-AIM Auction to conclude early are similar to those that would cause a simple AIM Auction to conclude early (as is currently the case),³⁹ except they are based on the entry of simple or complex orders that impact the SBBO or the best available prices on the same side of the COB rather than the BBO.

The Exchange proposes to conclude the C-AIM Auction in response to the incoming orders described above, as they would cause the SBBO or the best-priced complex order on the same side of the market as the Agency Order to be better priced than the stop price, or cause the stop price to be the same price as the SBBO with a Priority Customer order on the BBO for a component or a Priority Customer complex order on the COB. Similarly, the incoming orders described above would cause the opposite side SBBO to be at or better than the stop price. These events would create circumstances under which a C-AIM Auction would not have been initiated, and therefore, the Exchange believes it is appropriate to conclude a C-AIM Auction when they exist.

Additionally, the proposed rule change would conclude a C-AIM Auction in response to an incoming order that would cause the SBBO to be at a price not permissible under the Limit Up-Limit Down Plan or Regulation SHO,⁴⁰ and would conclude the C-AIM Auction without execution.

This will ensure that the stock leg of a stock-option order submitted into a C-AIM Auction does not execute at a price not permissible under that plan or regulation. This is consistent with current C-AIM functionality to ensure that stock legs do not trade at prices not permissible under the Limit Up-Limit Down Plan or Regulation SHO, and the proposed rule change codifies this in the Rules.

Proposed Rule 5.38(d)(2) states if the System receives an unrelated market or marketable limit complex order (against the SBBO or the best price of a complex order resting in the COB), including a Post Only complex order, on the opposite side of the market during a C-AIM Auction, the C-AIM Auction does not end early, and the System executes the order against interest outside the C-AIM Auction or posts the complex order to the COB. If contracts remain from the unrelated complex order at the time the C-AIM Auction ends, they may be allocated for execution against the Agency Order pursuant to proposed Rule 5.38(e). Because these orders may have the opportunity to trade against the Agency Order following the conclusion of the C-AIM Auction, which execution must still be at or better than the SBBO and the best-priced complex orders on the COB, the Exchange does not believe it is necessary to cause a C-AIM Auction to conclude early in the event the Exchange receives such orders. This will provide more time for potential price improvement, and the unrelated complex order will have the opportunity to trade against the Agency Order in the same manner as all other contra-side interest.⁴¹

At the conclusion of a C-AIM Auction, the System executes the Agency Order against the Initiating Order or contra-side complex interest in the same manner as it does today (and similar to the manner in which it executes a simple Agency Order).⁴² The Agency Order will execute at the best price(s), to the price at which the balance of the Agency Order can be fully executed (the “final auction price”). Any execution prices must be at or between the SBBO and the best prices of any complex orders resting on each side of the COB at the conclusion of the C-AIM Auction. This is consistent with executions following a C-AIM Auction today, which must be consistent with

complex order priority rules.⁴³ The proposed allocation of complex interest to an Agency Order at the conclusion of a C-AIM Auction is similar to the allocation of simple interest to an Agency Order at the conclusion of a simple AIM Auction, except the Exchange does not propose to make Priority Orders available in C-AIM, and does not offer complex reserve orders so there would be no displayed Reserve Quantity available on the COB for execution.⁴⁴

Unlike today, the Agency Order will only execute against the Initiating Order, C-AIM responses, and complex orders resting in the COB, and will not leg into the Simple Book, at the conclusion of a C-AIM Auction. As proposed, the execution prices for an Agency Order will always be better than the SBBO existing at the conclusion of the C-AIM Auction if it includes a Priority Customer order on any leg, and thus is consistent with general customer priority principles with respect to complex orders, pursuant to which complex orders may only trade against complex interest at prices that improve the BBO of any component that is represented by a Priority Customer order.⁴⁵

The Simple Book and the COB are separate, and orders on each do not interact unless a complex order legs into the Simple Book. As a result, the System is not able to calculate the aggregate size of complex auction responses and complex orders on the COB and the size of simple orders in the legs that comprise the complex strategy at each potential execution price (as executions may occur at multiple prices) prior to execution of an order following an auction for complex orders. The current priority following a C-AIM Auction provides that the System will first execute the complex order against all interest in the Simple Book, and then against interest in the COB.⁴⁶ If the Exchange were to permit legging into the Simple Book following a C-AIM Auction in accordance with the complex order allocation that will be in place following the technology migration,⁴⁷ the System would first look

⁴³ See current Rule 6.74A, Interpretation and Policy .08; see also current Rule 6.53C(d) and Interpretation and Policy .06.

⁴⁴ See Rule 5.37(e) in the shell Rulebook.

⁴⁵ See proposed Rule 5.38(e)(5).

⁴⁶ See current Rule 6.74A, Interpretation and Policy .08; see also current Rule 6.53C(d).

⁴⁷ As part of the Cboe Affiliated Exchanges' efforts to align certain system functionality, the Exchange intends to amend and move complex order rules from current Rule 6.53C in the current Rulebook to Rule 5.33 in the shell Rulebook, which rule would be substantively the same as EDGX Rule 21.20.

Continued

³⁹ See Rule 5.37(d) in the shell Rulebook.

⁴⁰ See current Rule 6.53C, Interpretation and Policy .06(f).

⁴¹ This is similar to the corresponding provision for simple AIM Auctions. See Rule 5.37(d)(2) in the shell Rulebook.

⁴² See proposed Rule 5.38(e).

to determine whether there are Priority Customer orders resting in the Simple Book at the final auction price (and in the applicable ratio). If there are, the System would execute the complex order against those simple orders. Following that execution, the System would then look back at C-AIM responses and complex orders resting in the COB to determine whether there is interest against which the order can execute. If there is, the System would execute the remaining portion of the complex order against that complex contra-side interest. Finally, if there is any size left, the System would look back at the Simple Book to determine whether any orders in the legs are able to trade against any remaining contracts in the complex order. If there is, the System would execute the remaining portion of the complex order again against orders in the Simple Book. Because of this process, prior to execution against any Priority Customer simple orders at a single price level, the System would not know the aggregate interest available on both the Simple Book and COB to execute against the auctioned order at that price level.

The amount of aggregate interest available to execute against the Agency Order is relevant in a C-AIM Auction with respect to the allocation of contracts against the Agency Order and other interest at each price level, and with respect to determining the final price level at which the Agency Order will execute. For example, when auto-match is selected, because the System will not be able to determine the aggregate size of contra-side interest (including simple and complex) at that price level, it would not be able to determine how many contracts of the Agency Order should execute against the Initiating Order (which should equal the aggregate size of that contra-side

interest). Additionally, because the System will not be able to determine the aggregate size of contra-side interest (including simple and complex) at the stop price, it would not be able to determine the applicable percentage of the Agency Order that should execute against the Initiating Order.

The Exchange notes there would be significant technical complexities associated with reprogramming priority within the System to permit Agency Orders to leg into the Simple Book following a C-AIM Auction and allocate the Agency Order in a manner consistent with standard priority principles and crossing auctions, while making the most crossing functionality available to TPHs. The proposed rule change will ensure the Agency Order executes in accordance with the C-AIM allocation principles (which are consistent with AIM allocation principles), which provide Priority Customers with priority over the Initiating Order (and other contra-side interest) but also provide for the Initiating Order to execute against a certain portion of the Agency Order, as well as provide Initiating TPHs with flexibility to submit single-price submissions or auto-match at multiple price levels. The Exchange believes providing this functionality will encourage TPHs to submit complex orders into C-AIM Auctions and provide customer orders with opportunities for price improvement. It will also ensure orders (including Priority Customer orders) on the Simple Book are protected in accordance with standard complex order priority principles, as an Agency Order will only be permitted to execute at prices that do not trade at the SBBO existing at the conclusion of the C-AIM Auction if it includes a Priority Customer order on any leg, and that do not trade through the SBBO existing at the conclusion of the C-AIM Auction.

As noted above, the stop price of the Agency Order must be better than the same and opposite side of the SBBO if there is a Priority Customer order at the BBO in any component of the complex strategy. Additionally, the stop price must be better than the price of any Priority Customer order resting at the top of the COB on the same side as the Agency Order. Further, a C-AIM Auction will conclude upon receipt of an unrelated Priority Customer order in any component of the complex strategy that would post to the Simple Book and cause the SBBO on either side of the Agency Order to be equal to or better than the stop price, or upon the receipt of an unrelated Priority Customer complex order on the same side as the

Agency Order that post to the COB with a price equal to or better than the stop price. Additionally, any execution prices at the conclusion of the C-AIM Auction will be subject to the standard complex order priority rules in Rule 5.33 in the shell Rulebook,⁴⁸ which ensures an Agency Order must execute at a price that improves the SBBO if there is a Priority Customer order at the BBO in any leg.⁴⁹ Therefore, the proposed rule change protects Priority Customer orders in the Simple Book even though Agency Orders may not leg into the Simple Book.

Proposed Rule 5.38(f) regarding Customer-to-Customer C-AIM Immediate crosses is consistent with current functionality, and merely adds detail regarding the current price restrictions applicable to these executions.⁵⁰

Proposed Rule 5.38, Interpretations and Policies .01 through .03 are the same as current Rule 6.74A, Interpretations and Policies .01, .02, and .08, which currently apply to AIM Auctions for complex orders.⁵¹

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the “Act”) and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.⁵² Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)⁵³ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling,

⁴⁸ See *id.*

⁴⁹ If there was a Priority Customer order resting at the BBO in any leg of a complex strategy in the Simple Book, and a complex order was submitted to the Exchange (outside of a C-AIM Auction) with a price one minimum increment better than the SBBO, that complex order would not be able to execute against interest in the leg markets (including the Priority Customer order).

⁵⁰ See current Rule 6.74A, Interpretation and Policy .08(b). The Exchange notes, pursuant to current Rule 6.74A, Interpretation and Policy .08(b), it has not designated any class in which complex orders are eligible for AIM customer-to-customer immediate crosses. Following the technology migration, the Exchange intends to make customer-to-customer immediate crosses for complex orders available in any class in which the Exchange designates as eligible for C-AIM Auctions pursuant to proposed Rule 5.38(a).

⁵¹ These provisions are also virtually identical to the ones applicable to simple AIM Auctions. See Rule 5.37, Interpretations and Policies .01 through .03 in the shell Rulebook.

⁵² 15 U.S.C. 78f(b).

⁵³ 15 U.S.C. 78f(b)(5).

Proposed Rule 5.38(e)(5) explicitly states that execution following a C-AIM Auction for a complex Agency Order will be subject to the complex order price restrictions and priority in Rule 5.33(f)(2). Pursuant to EDGX Rule 21.20(f)(2) (the Exchange intends to adopt an identical provision), the System will not execute a complex order at a net price (i) that would cause any component of the complex strategy to be executed at a price of zero; (ii) worse than the SBBO or equal to the SBBO when there is a Priority Customer Order at the SBBO, except AON complex orders may only execute at prices better than the SBBO; (iii) that would cause any component of the complex strategy to be executed at a price worse than the individual component prices on the Simple Book; (iv) worse than the price that would be available if the complex order Legged into the Simple Book; or (v) that would cause any component of the complex strategy to be executed at a price ahead of a Priority Customer Order on the Simple Book without improving the BBO of at least one component of the complex strategy. The proposed execution provisions for C-AIM Auctions are consistent with this priority.

processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)⁵⁴ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The proposed rule change is generally intended to align certain system functionality currently offered by Cboe Options to the Exchange's System in order to provide a consistent technology offering for the Cboe Affiliated Exchanges. A consistent technology offering, in turn, will simplify the technology implementation, changes and maintenance by Users of the Exchange that are also participants on Cboe Affiliated Exchanges. This will provide Users with greater harmonization of price improvement auction mechanisms available among the Cboe Affiliated Exchanges.

The Exchange's C-AIM will function in a substantially similar manner following the technology migration as it does today. The proposed rule change clarifies in the Rules that the Initiating Order may be comprised of multiple contra-party orders will benefit investors. As noted above, this is consistent with current functionality, and the proposed rule change merely adds this detail to the rule, which additional transparency will benefit investors. Permitting the Initiating Order to be comprised of multiple contra-party orders may increase the opportunity for customers to have orders participate in a C-AIM auction. As a result, this may increase opportunities for price improvement, because this will increase the liquidity available for the Initiating Order, which is consistent with the purpose of C-AIM Auctions. The Exchange believes that this is beneficial to participants because allowing multiple contra-parties should foster competition for filling the Initiating Order and thereby result in potentially better prices, as opposed to only allowing one contra-party and, thereby requiring that contra-party to do a larger size order which could result in a worse price for the trade.

The proposed rule change to prohibit Initiating TPHs from designating an Agency Order or Initiating Order as Post Only is appropriate, as the purpose of a Post Only order is to not execute upon entry and instead rest in the Book, while

the purpose of a C-AIM Auction is to receive an execution following the Auction but prior to entering the Book.

The proposed rule change to require the stop price to be at least one minimum increment better than the best-priced complex order in the COB, unless the Agency Order is a Priority Customer order and the resting order is not a Priority Customer, in which case the stop price must be at or better than the price of the complex order will protect investors. It will protect Priority Customer orders on the same side of the COB, as the current rule does, except it does so by applying a check at the initiation of a C-AIM Auction rather than at the conclusion of the Auction. By permitting a Priority Customer Agency Order to trade at the same price as a resting non-Priority Customer order, the proposed rule change also protects Priority Customer orders submitted into a C-AIM Auction. Additionally, application of this check at the initiation of a C-AIM Auction may result in the Agency Order executing at a better price, since the stop price must improve any same-side orders (with the exception of a Priority Customer Agency Order and a resting non-Priority Customer order described above), as under the current Rule, the Agency Order may execute at one minimum increment worse. The proposed rule change is consistent with general customer priority principles.

As noted above, the proposed rule change will allow C-AIM Auctions for which the smallest leg is for 50 standard option contracts (or 500 mini-option contracts) or more to occur concurrently with other C-AIM Auctions. Although C-AIM Auctions for larger Agency Orders will be allowed to overlap, the Exchange does not believe that this raises any issues that are not addressed by the proposed rule change. For example, although overlapping, each C-AIM Auction will be started in a sequence and with a time that will determine its processing. Thus, even if there are two C-AIM Auctions that commence and conclude, at nearly the same time, each C-AIM Auction will have a distinct conclusion at which time the Auction will be allocated. In turn, when the first C-AIM Auction concludes, unrelated orders that then exist will be considered for participation in the Auction. If unrelated orders are fully executed in such C-AIM Auction, then there will be no unrelated orders for consideration when the subsequent Auction is processed (unless new unrelated order interest has arrived). If instead there is remaining unrelated order interest after the first C-AIM Auction has been

allocated, then such unrelated order interest will be considered for allocation when the subsequent Auction is processed. As another example, each C-AIM response is required to specifically identify the Auction for which it is targeted and if not fully executed will be cancelled back at the conclusion of the Auction. Thus, C-AIM responses will be specifically considered only in the specified Auction.

The proposed rule change to allow multiple auctions to overlap for Agency Orders of 50 standard option contracts (or 500 mini-option contracts) or more is consistent with functionality already in place on other exchanges.⁵⁵ Different complex strategies are essentially different products—orders in different strategies cannot interact, just as orders in different classes or series cannot interact. Therefore, the Exchange believes concurrent C-AIM Auctions in different complex strategies is appropriate. Additionally, while it is possible for a complex order to leg into the Simple Book, a complex order may only execute against simple orders if there is interest in each component in the ratio of the complex strategy. A simple order in one component of a complex strategy cannot on its own interact with a complex order in that complex strategy. Therefore, the Exchange believes it is appropriate to permit concurrent C-AIM Auctions in the same component. As proposed, C-AIM Auctions will ensure that Agency Orders execute at prices that protect Priority Customer orders in the Simple Book and that are not inferior to the SBBO, even when there are concurrent Auctions occurring. The proposed rule change sets forth how any Auctions with overlapping complex strategies or overlapping components will conclude if terminated due to the same event. The Rules do not currently prevent a COA in a complex strategy from occurring at the same time as an AIM in one of the components of the complex strategy. Therefore, the Exchange believes it is similarly reasonable to permit multiple C-AIM in a complex strategy to occur at the same time as an AIM in one of the components of the complex strategy. The Exchange believes this new functionality may lead to an increase in Exchange volume and should allow the Exchange to better compete against other markets that permit overlapping

⁵⁵ See, e.g., EDGX Rule 21.22(c)(1); see also, e.g., Nasdaq ISE LLC ("ISE") Rules 716(d) and 723, Interpretation and Policy .04; and Boston Options Exchange LLC ("BOX") Rule 7270 and BOX IM-7150-3.

⁵⁴ *Id.*

price improvement auctions, while providing an opportunity for price improvement for Agency Orders and assuring that Priority Customers on the simple Book and COB are protected.

The proposed rule change to permit all Users to respond to C-AIM Auctions will benefit investors. Permitting all Users to submit responses to C-AIM Auctions, rather than appointed Market-Makers and TPHs representing orders as agent at the top of the Book or COB, may result in more Users having the opportunity to participate in executions at the conclusion of C-AIM Auctions. Additionally, it may increase liquidity in C-AIM Auctions, which may lead to more opportunities to [sic] price improvement. The Exchange believes the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and a national market system, because other exchanges permit all market participants to respond to similar price improvement auctions.⁵⁶

The proposed rule changes regarding permissible designations on responses are reasonable and promote a fair and orderly market, because they are consistent with the general auction functionality. The proposed rule change that prohibits Users from designating a C-AIM Auction response with an MTP Modifier other than MTP Cancel Newest is consistent with the prohibition on the Agency Order being cancelled after it is submitted. Additionally, the proposed rule change that prohibits Users from designating a response as IOC is reasonable, because it is consistent with the purpose of an AIM response, which is to potentially execute against an Agency Order at the conclusion of a C-AIM Auction (and thus not immediately upon entry, as required by the time-in-force of IOC).

The proposed events that will conclude a C-AIM Auction are reasonable and promote a fair and orderly market and national market system, because they will ensure that executions at the conclusion of an Auction occur at permissible prices (such as not outside the SBBO (and not at the SBBO if there is a Priority Customer order in any component on the Simple Book) and not at the same price as a Priority Customer order on the COB). The proposed rule change will also benefit investors by providing clarity regarding what will cause a C-AIM Auction to conclude. These events would create circumstances under which a C-AIM Auction would not have been permitted to start, or that would cause the auction price no longer

be consistent with the permissible prices at which executions at the conclusion of an Auction may occur. Thus the Exchange believes it is appropriate to conclude a C-AIM Auction if those circumstances occur. The Exchange will no longer conclude a C-AIM Auction early due to the receipt of an opposite side complex order other than one proposed instance. The Exchange believes this promotes just and equitable principles of trade, because these orders may have the opportunity to trade against the Agency Order following the conclusion of the Auction, which execution must still be at or better than the SBBO, as well as prices of complex orders in the COB. The Exchange believes this will protect investors, because it will provide more time for price improvement, and the unrelated order will have the opportunity to trade against the Agency Order in the same manner as all other contra-side complex interest.

The Exchange believes the proposed execution of Agency Orders are reasonable and promote a fair and orderly market and national market system, because best-priced contra-side interest executes against the Agency Order first, and Priority Customer complex orders will have first priority at each price level, followed by other contra-side complex interest. The proposed rule change does not adopt Priority Order status for C-AIM, which is only available in simple AIM for classes the Exchange designates.

In a separate rule filing, the Exchange intends to adopt complex order allocation rules consistent with those in EDGX Options Rule 21.20 as part of its efforts to harmonize rules and functionality across the Cboe Affiliated Exchanges. Pursuant to that rule, if an order is able to leg into the Simple Book, the System would first execute an order against Priority Customer orders in the Simple Book, then against any complex order interest in the COB (or auction responses), and last against any other simple interest in the Simple Book (with executions against the Simple Book occurring in the applicable ratio). This would occur at each price at which the complex order may execute. Requiring the System to make these determinations by going “back and forth” between the Simple Book and the COB at multiple price levels would be more complicated after a C-AIM Auction. The System must determine the aggregate amount of interest available at each execution price level before executing any portion of the Agency Order to determine the final auction price and how to allocate the Agency Order against contra-side

interest at the conclusion of a C-AIM Auction. This is necessary because the System must determine at each price level the aggregate non-Priority Customer interest to calculate any auto-match amounts, and to determine the aggregate number of contracts remaining in the Agency Order at the final auction price to calculate the allocation percentage for the Initiating Order.

There would be significant technical complexities associated with reprogramming priority within the System to permit Agency Orders to leg into the Simple Book following a C-AIM Auction and allocate the Agency Order in a manner consistent with standard priority principles and crossing auctions, while making the most crossing functionality available to TPHs. As discussed above, the Exchange believes the proposed rule change protects Priority Customer orders on the Simple Book, because executions following a C-AIM Auction are subject to the general complex order priority⁵⁷ that will apply to executions of all complex orders on the Exchange. It ensures an Agency Order will only execute at prices better than the SBBO existing at the conclusion of the C-AIM Auction if there is a Priority Customer order at the BBO on any leg, and at prices equal to or better than the SBBO existing at the conclusion of the C-AIM Auction if there is no Priority Customer order at the BBO on any leg. The proposed allocation will also ensure the Agency Order does not trade at the same price as a Priority Customer complex order resting on the COB or through the best-priced complex orders on the COB, and will protect investors by providing Priority Customer complex orders with priority at each price level.

Given the infrequency with which complex orders currently leg into the Simple Book, including at the conclusion of C-AIM Auctions for complex orders, the Exchange believes it is in the best interest of investors to not implement additional technical complexities given the expected minimal impact, if any, that not permitting Agency Orders to leg into the Simple Book following a C-AIM Auction would have on execution opportunities for orders in the Simple Book.⁵⁸

⁵⁷ See proposed Rule 5.38(e)(5) and *supra* note 47.

⁵⁸ The Exchange notes the complex order crossing auctions of other options exchanges do not leg agency orders into the simple book at the conclusion of the auction as long as there is price improvement over the equivalent of the SBBO for that exchange. See, e.g., EDGX Options Rule 21.22(e); and NYSE American, LLC (“Amex”) Rule 971.2NY(c)(4).

⁵⁶ See, e.g., EDGX Options Rule 21.22(c)(5).

The Exchange believes the proposed rule changes that add detail to the Rules, which are consistent with current functionality, will remove impediments to and perfect the mechanism of a free and open market and protect investors, as these changes provide transparency in the Rules regarding C-AIM Auctions. Additionally, the proposed rule change aligns rule language with corresponding provisions in EDGX Options Rule 21.22.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the proposed rule change to amend the C-AIM Auction will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, as the proposed changes to the C-AIM Auction will apply to all orders submitted to an Auction in the same manner. C-AIM Auctions will continue to be voluntary for TPHs to use, and are available to all TPHs. The Exchange does not believe the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because the proposed changes are substantially the same as another options exchange's rules.⁵⁹ The general framework and primary features of the Exchange's current C-AIM Auction is not changing, and will continue to protect orders, including Priority Customer orders, resting in the Book and the COB.

The Exchange does not believe the proposed rule change to permit all Users to respond to C-AIM Auctions will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because it will permits more types of market participants (*i.e.*, all Users) to submit responses to C-AIM Auctions, rather than just appointed Market-Makers and TPHs acting as agent for orders at the top of the Book or COB. This may result in more Users having the opportunity to participate in executions at the conclusion of C-AIM Auctions. The Exchange does not believe the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because it may increase liquidity in C-AIM

Auctions, which may lead to more opportunities to price improvement. Additionally, other exchanges permit all market participants to respond to similar price improvement auctions.⁶⁰

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

A. Significantly affect the protection of investors or the public interest;

B. impose any significant burden on competition; and

C. become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act⁶¹ and Rule 19b-4(f)(6)⁶² thereunder.⁶³ At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or

⁶⁰ See, e.g., EDGX Options Rule 21.19.

⁶¹ 15 U.S.C. 78s(b)(3)(A).

⁶² 17 CFR 240.19b-4(f)(6).

⁶³ 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.

- Send an email to rule-comments@sec.gov. Please include File Number SR-CBOE-2019-051 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-CBOE-2019-051. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of 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-CBOE-2019-051, and should be submitted on or before October 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶⁴

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019-19901 Filed 9-13-19; 8:45 am]

BILLING CODE 8011-01-P

⁵⁹ See EDGX Options Rule 21.22; see also Amex Rule 971.2NY(c)(4).

⁶⁴ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86784; File No. SR–NYSE–2019–45]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Price List To Remove and Adding Liquidity Tiers for Tape B and C Securities

Correction

In notice document 2019–18999 beginning on page 46588 in the issue of Wednesday, September 4, 2019, make the following correction:

On page 46593, in the third column, in the first paragraph, starting in the two last lines “September 24, 2019” should read “September 25, 2019”.

[FR Doc. C1–2019–18999 Filed 9–13–19; 8:45 am]

BILLING CODE 1301–00–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Regulation S–AM, SEC File No. 270–548, OMB Control No. 3235–0609

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (“PRA”) (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (“Commission”) is soliciting comments on the existing collection of information provided for in Regulation S–AM (17 CFR part 248, subpart B), under the Fair Credit Reporting Act (15 U.S.C. 1681 *et seq.*) (“FCRA”), the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*), the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*), and the Investment Advisers Act of 1940 (15 U.S.C. 80b–1 *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (“OMB”) for extension and approval.

Regulation S–AM implements the requirements of Section 624 of the FCRA (15 U.S.C. 1681s–3) with respect to investment advisers and transfer agents registered with the Commission, as well as brokers, dealers and investment companies (collectively, “Covered Persons”). Section 624 and Regulation S–AM limit a Covered

Person’s use of certain consumer financial information received from an affiliate to solicit a consumer for marketing purposes, unless the consumer has been given notice and a reasonable opportunity and a reasonable and simple method to opt out of such solicitations. Regulation S–AM potentially applies to all of the approximately 20,195 Covered Persons registered with the Commission, although only approximately 11,309 of them have one or more corporate affiliates, and the regulation requires only approximately 2,020 to provide consumers with an affiliate marketing notice and an opt-out opportunity.

The Commission staff estimates that there are approximately 11,309 Covered Persons having one or more affiliates, and that they each spend an average of 0.20 hours per year to review affiliate marketing practices, for, collectively, an estimated annual time burden of 2,262 hours at an annual internal compliance cost of approximately \$1,203,384. The staff also estimates that approximately 2,020 Covered Persons provide notice and opt-out opportunities to consumers, and that they each spend an average of 7.6 hours per year creating notices, providing notices and opt-out opportunities, monitoring the opt-out notice process, making and updating records of opt-out elections, and addressing consumer questions and concerns about opt-out notices, for, collectively, an estimated annual time burden of 15,352 hours at an annual internal compliance cost of approximately \$2,999,296. Thus, the staff estimates that the collection of information requires a total of approximately 11,309 respondents to incur an estimated annual time burden of a total of 17,614 hours at a total annual internal cost of compliance of approximately \$4,202,680.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission’s estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549, or send an email to: PRA_Mailbox@sec.gov.

Dated: September 11, 2019.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–19971 Filed 9–13–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86923; File No. SR–CBOE–2019–057]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Regarding Price Protections and Risk Controls

September 10, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on September 5, 2019, Cboe Exchange, Inc. (the “Exchange” or “Cboe Options”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a “non-controversial” proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³ and Rule 19b–4(f)(6) thereunder.⁴ 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 the Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the “Exchange” or “Cboe Options”) proposes to amend the Exchange’s Rules regarding price protections and risk controls, and moves those Rules from the currently effective Rulebook (“current Rulebook”) to the shell structure for the Exchange’s Rulebook that will become effective upon the migration of the Exchange’s trading platform to the same system

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴ 17 CFR 240.19b–4(f)(6).

used by the Cboe Affiliated Exchanges (as defined below) (“shell Rulebook”). The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange’s website (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange’s Office of the Secretary, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In 2016, the Exchange’s parent company, Cboe Global Markets, Inc. (formerly named CBOE Holdings, Inc.)

(“Cboe Global”), which is also the parent company of Cboe C2 Exchange, Inc. (“C2”), acquired Cboe EDGA Exchange, Inc. (“EDGA”), Cboe EDGX Exchange, Inc. (“EDGX” or “EDGX Options”), Cboe BZX Exchange, Inc. (“BZX” or “BZX Options”), and Cboe BYX Exchange, Inc. (“BYX” and, together with Cboe Options, C2, EDGX, EDGA, and BZX, the “Cboe Affiliated Exchanges”). The Cboe Affiliated Exchanges are working to align certain system functionality, retaining only intended differences between the Cboe Affiliated Exchanges, in the context of a technology migration. Cboe Options intends to migrate its trading platform to the same system used by the Cboe Affiliated Exchanges, which the Exchange expects to complete on October 7, 2019. In connection with this technology migration, the Exchange has a shell Rulebook that resides alongside its current Rulebook, which shell Rulebook will contain the Rules that will be in place upon completion of the Cboe Options technology migration.

The Exchange proposes to harmonize its rules in connection with the risk control and price protection functions on the Exchange to that of its affiliated Exchanges. Specifically, the Exchange proposes to consolidate all order and quote price protection mechanisms and risk controls into a single rule, proposed Rule 5.34 (and subsequently delete the relevant price protection mechanism and risk control provisions in current

Rules 6.12, 6.13, 6.14, 6.23C, and 6.53C.08 upon migration). Proposed Rule 5.34 is substantively identical to C2 Rule 6.14, as well as substantially the same as corresponding EDGX Options Rules 21.16, 21.17 and 22.11. In line with C2 Rule 6.14, proposed Rule 5.34 categorizes these mechanisms and controls as ones applicable to simple orders (proposed paragraph (a)), complex orders (proposed paragraph (b)), and all (*i.e.* simple and complex) orders (proposed paragraph (c)). The following table identifies the Exchange’s current price protection mechanisms and risk controls, the current Exchange Rule, the proposed Exchange Rule, the corresponding C2 Rule and EDGX rule, where applicable, and any proposed changes, if any. The Exchange notes that much of the proposed functionality is substantially similar to the current price protections and risk controls functionality. The Exchange also proposes to make non-substantive changes by updating cross-references to rules in the shell Rulebook and rules not yet in the shell Rulebook but that in the Exchange intends to move to the shell Rulebook, updating Exchange-specific references for consistency throughout the rules, and, as a result of consolidating and conforming the proposed rule to the rules of affiliated options exchanges, simplifies, clarifies, and updates the rule text to read in plain English, and reformats the paragraph lettering and/or numbering.

Price protection/ risk control	Current Cboe options rule	Proposed rule	Affiliated exchange rule	Proposed changes
Handling of market orders received in no-bid series.	6.13(b)(vi)	5.34(a)(1) ...	C2 Rule 6.14(a)(1); EDGX Rule 21.17(a)(5).	Pursuant to the proposed rule change, the System cancels or rejects a market order if there is no-bid and the best offer is less than or equal to \$0.50. Under current functionality, the System would treat the sell order as a limit order with a price equal to the minimum increment in this situation. The proposed rule change also expands the same protection to market orders in no-offer series. The Exchange believes the proposed rule change will provide protection for these orders to prevent execution at potentially erroneous prices when a market order is entered in a series with no bid or offer.
Market order NBBO width protection.	6.13(b)(v)(A)	5.34(a)(2) ...	C2 Rule 6.14(a)(2); EDGX 21.17(a)(1).	The proposed functionality is generally the same as current functionality, except the acceptable amount away from NBBO that a market order may execute will be determined by a percentage away from the NBBO midpoint (subject to a minimum and maximum dollar amount) rather than specified dollar ranges based on premium, providing the Exchange with flexibility it believes is appropriate given previous experience with risk controls.
Buy order put check	6.14(a)	5.34(a)(3) ...	C2 6.14(a)(3); EDGX 21.17(a)(3).	The proposed rule change will apply to market order executions during the Opening Process, and deletes the call underlying value check in current Rule 6.17(a)(i)(B), as this functionality will not be available on the Exchange’s new system following the technology migration.
Drill-through protection (simple).	6.13(b)(v)(B)	5.34(a)(4) ...	C2 6.14(a)(4); EDGX 21.17(a)(4).	The proposed functionality is generally the same as current functionality, except the drill-through amount is a buffer amount determined by class and premium rather than a number ticks. The proposed rule change deletes the distinction between orders exposed via HAL, which is in line with current functionality on EDGX, which provides for the HAL equivalent, SUM. The proposed functionality applies to Day orders, as well as Good-til-Date (“GTD”) and Good-til-Cancel (“GTC”) orders that re-enter the Book from the prior trading day, but not an Immediate-or-Cancel (“IOC”) or Fill-or-Kill (“FOK”) order, as resting in the Book for a period of time is inconsistent with their purpose (which is to cancel if not executed immediately).

Price protection/ risk control	Current Cboe options rule	Proposed rule	Affiliated exchange rule	Proposed changes
Bulk message fat finger check.	N/A	5.34(a)(5) ...	C2 6.14(a)(5); EDGX 21.17(a)(6).	The proposed functionality adds a price protection mechanism for bulk messages similar to the fat finger check the Exchange currently provides for orders. The proposed rule states the System cancels or rejects any bulk message bid (offer) above (below) the NBO (NBB) by more than a specified amount determined by the Exchange. The proposed check also will not apply to bulk messages submitted prior to the conclusion of the Opening Process or when no NBBO is available, which is appropriate during the pre-open or opening rotation so that the check does not impact the determination of the opening price, and also when there is no NBBO, as the Exchange believes that it is the most reliable measure against which to compare the price of the bulk message to determine its reasonability.
Definitions of vertical spread, butterfly spread, and box spread.	6.53C.08	5.34(b)(1) ...	C2 6.14(b)(1); EDGX 21.17(b)(1).	No substantive changes.
Credit-to-debit parameters.	6.53C.08(b)	5.34(b)(2) ...	C2 6.14(b)(2); EDGX 21.17(b)(2).	No substantive changes.
Debit/credit price reasonability checks.	6.53C.08(c)	5.34(b)(3) ...	C2 6.14(b)(3); EDGX 21.17(b)(3).	The proposed functionality is generally the same as current functionality, except the acceptable price is subject to a pre-set buffer amount, which flexibility is consistent with C2 and EDGX functionality. The proposed rule also adopts language that accounts for the stock component of a stock-option order, which is consistent with EDGX Rule 21.17 (and not found within C2 Rule 6.14 because C2 does not currently provide for this functionality). The check will apply to multi-class spreads because, upon migration, such orders will be routed to PAR to which the price protections and risk controls under the proposed rule will apply.
Buy strategy parameters	6.53C.08(d)	5.34(b)(4) ...	C2 6.14(b)(4); EDGX 21.17(b)(4).	The proposed functionality is generally the same as current functionality, except the net credit price is subject to a buffer amount (consistent with C2 and EDGX functionality). The proposed rule change deletes the mechanism's applicability to sell strategies, as that functionality will not be available on the Exchange following the technology migration. The Exchange also uses proposed term "minimum increment" as opposed to "\$0.01" as some classes move in increments that differ from a penny.
Maximum value acceptable price range.	6.53C.08(g)	5.34(b)(5) ...	C2 6.14(b)(5); EDGX 21.17(b)(5).	The proposed functionality is generally the same as current functionality, except the price range is calculated using a buffer amount (consistent with C2 and EDGX functionality) rather than a percentage amount.
Drill-through protection (complex).	N/A	5.34(b)(6) ...	C2 6.14(b)(6); EDGX 21.17(b)(6).	The proposed functionality is generally the same as current functionality that applies to simple orders, and expands it to complex orders. The proposed rule change replaces market width parameter protection and acceptable percentage range parameter in current Rule 6.53C.08(a) and (e), respectively, which currently protect Cboe Options complex orders from executing at potentially erroneous prices too far away from the order's price or the market's best price. The proposed rule is identical to the corresponding C2 and EDGX rules, which adds the concept that an order eligible for complex order request for responses auction process ("COA") would initiate a COA at the drill-through price as the prices for complex strategy executions may be subject to the drill-through protection, and the price of a COA may be impacted by the drill-through protection; and (2) describes how a change in the SBBO prior to the end of the time period but the complex order cannot Leg, and the new SBO (SBB) crosses the drill-through price, the System changes the displayed price of the complex order to the new SBO (SBB) minus (plus) \$0.01, and the order will not be cancelled at the end of the time period. The proposed rule change merely permits an order to remain on the complex order book ("COB") since the market reflects interest to trade (but not currently executable due to Legging Restrictions) that was not there at the beginning of the time period, providing additional execution opportunities prior to cancellation.
Limit Order Fat Finger Check.	6.12(a)(3) and 6.12(b).	5.34(c)(1) ...	C2 6.14(c)(1); EDGX 21.17(a)(2) & (b)(7).	The proposed functionality is generally the same as current functionality, except the amount away from the NBBO a limit order price may be is a buffer amount rather than a number of ticks with no minimum, and Exchange may determine whether the check applies to simple orders prior to the conclusion of the RTH opening auction process (current rules codify pre-open application), providing the Exchange with flexibility it believes appropriate given previous experience with risk controls. The proposed rule change does not apply to GTC or GTD orders that reenter the Book from the prior trading day, as this check only applies to orders when the System receives them. The proposed rule change provides Users with the ability to set a different buffer amount to accommodate its own risk modeling; does not apply to adjusted series prior to the RTH opening auction process, as prices may reflect the corporate action for the underlying but the previous day's NBBO would not reflect that action. If the check applies prior to the RTH opening auction process, the System compares the last disseminated NBBO on that trading day, or the midpoint of the prior trading day's closing NBBO, if no NBBO has been disseminated on that trading day, which the Exchange believes is another reasonable price comparison.
Maximum contract size	6.14(e)	5.34(c)(2) ...	C2 6.14(c)(2); EDGX 21.17(b)(8).	The proposed functionality is generally the same as current functionality, except the Exchange will set a default amount rather than permit User to set amount. The proposed rule change applies per port rather than acronym or login. The functionality to cancel a resting order or quote if replacement order or quote is entered will not be available on the Exchange following the technology migration (however, a User can enable cancel on reject functionality described below to receive same result).
Maximum notional value	N/A	5.34(c)(3) ...	C2 6.14(c)(3); EDGX Technical specifications.	Voluntary functionality similar to maximum contract size, except the System cancels or rejects an incoming order or quote with a notional value that exceeds the maximum notional value a User establishes for each of its ports. The proposed rule change provides an additional, voluntary control for Users to manage their order and execution risk on the Exchange.

Price protection/ risk control	Current Cboe options rule	Proposed rule	Affiliated exchange rule	Proposed changes
Daily risk limits	N/A	5.34(c)(4)	C2 6.14(c)(4); EDGX Technical specifications.	Voluntary functionality pursuant to which a User may establish limits for cumulative notional booked bid ("CBB") or offer ("CBO") value, and cumulative notional executed bid ("CEB") or offer ("CEO") value for each of its ports on a net or gross basis, or both, and may establish limits for market or limit orders (counting both simple and complex), or both. If a User exceeds a cutoff value (by aggregating amounts across the User's ports), the System cancels or rejects incoming limit or market orders, or both, as applicable. ⁶
Risk monitor mechanism	6.14(d) and 8.18.	5.34(c)(5)	C2 6.14(c)(5); EDGX 21.16.	Similar functionality to current quote risk monitor and order entry, execution, and price parameter rate checks on the Exchange, which will not be available on the Exchange following migration (discussed below).
Cancel on reject	N/A	5.34(c)(6)	C2 6.14(c)(6); EDGX 6.14(a)(7).	Additional, voluntary control for Users to manage their order and execution risk on the Exchange, pursuant to which the System cancels a resting order or quote if the System rejects a cancel or modification instruction (because, for example, it had an invalid instruction) for that resting order or quote. The proposed rule change is consistent with the purpose of a cancel or modification, which is to cancel the resting order or quote, and carries out this purpose despite an erroneous instruction on the cancel/modification message.
Kill switch	6.14(f)	5.34(c)(7)	C2 6.14(c)(7); EDGX 22.11.	The proposed functionality is generally the same as current functionality, except Users may apply it to different categories of orders by EFID rather than acronym or login (consistent with new System functionality for migration), and block of incoming orders or quotes is a separate request by Users.
Cancel on disconnect	6.23C	5.34(c)(8)	C2 6.14(c)(8); EDGX Technical Specifications.	The proposed functionality is generally the same as current technical disconnect functionality, except it is the same for both APIs on the new System. The proposed rule change will continue to protect Users against erroneous executions if it appears they are experiencing a system disruption. The proposed functionality will no longer provide TPHs with the ability to determine length of interval, but does provide additional flexibility with respect to which order types may be cancelled—current functionality permits a choice of market-maker quotes and day orders, while the proposed functionality permits a choice of day and GTC/GTD orders, or just day orders.
Block new orders	N/A	5.34(c)(9)	C2 6.14(c)(9); EDGX 22.11.	Similar to automatic functionality that occurs on the Exchange currently when a Trading Permit Holder uses kill switch functionality. The proposed rule change merely provides a separate way to achieve this result on the new System, providing Users with flexibility regarding how to manage their resting orders and quotes.
Duplicate order protection.	N/A	5.34(c)(10) ..	C2 6.14(c)(10); EDGX Technical specifications.	Additional, voluntary control for Users to manage their order and execution risk on the Exchange. The proposed rule change protects Users against execution of multiple orders that may have been erroneously entered.
Buy-Write/Married Put Check.	6.53C.08(a)(5)	5.34(c)(11) ..	EGDX 21.17(b)(9).	The proposed functionality is generally the same as current functionality, the acceptable price range is based on the price of the call (put) plus (minus) an Exchange-determined buffer amount.

The price protection mechanisms and risk controls under proposed Rule 5.34 are applicable to the System's acceptance and execution of orders and quotes pursuant to the Rules, including Rules 5.31 through 5.33,⁷ and to and orders routed to the Exchange's Public Automated Routing System ("PAR")

⁵ See Rule 5.6 in the shell Rulebook. For an order designated as a GTD order, if after entry into the System, the order is not fully executed, the order (or unexecuted portion) remains available for potential display or execution (with the same timestamp) until a date and time specified by the entering User unless cancelled by the entering User. For an order designated as a GTC order, if after entry into the System, the order is not fully executed, the order (or unexecuted portion) remains available for potential display or execution (with the same timestamp) unless cancelled by the entering User, or until the option expires, whichever comes first.

⁶ The System calculates a notional cutoff on a gross basis by summing CBB, CBO, CEB, and CEO. The System calculates a notional cutoff on a net basis by summing CEO and CBO, then subtracting the sum of CEB and CBB, and then taking the absolute value of the resulting amount.

⁷ Rules to be effective on October 7, 2019 and cover the opening auction process, order and quote book processing, display, priority, and execution, as well as complex orders.

pursuant to Rule 5.82.⁸ The Exchange notes that the proposed rule's inclusion of PAR orders is an intended difference made between its proposed rule and C2's rule, as PAR is unique to the Exchange. Upon migration, all orders routed to PAR will also be subject to price protection mechanisms and risk controls. This will provide the same protections for User's PAR routed order as for User's order and quotes sent through and executed by the System. Currently, PAR functions outside of the System, therefore not all risk controls are currently applicable to PAR orders. Upon migration, PAR orders will be entered into the System in the same manner as all other orders, and will route to PAR per User instruction, after going through the System, therefore, the same price protection mechanisms and risk controls will apply.

The proposed rule change also deletes the mechanisms related to execution of quotes that lock or cross the NBBO and quotes inverting the NBBO (current Rule 6.14(b) and (c)). The Exchange's current

quote functionality will be replaced with bulk message functionality⁹ upon migration; however, orders and bulk messages (the equivalent of current quotes) submitted by Market-Makers will be subject to the same protections, except for those that do not apply to bulk messages (e.g., for market orders in no-bid (offer) series, market order NBBO width and drill-through protections, limit order fat finger checks, and daily risk limits) as described above.

Under the current C2 and EDGX debit/credit price reasonability check (see C2 Rule 6.14(b)(3) and EDGX Rule 21.17(b)(3)), the System only pairs calls (puts) if they have the same expiration date but different exercise prices or the same exercise price but different expiration dates. Under the Exchange's

⁹ See Rule 1.1 in shell Rulebook, which states that "bulk message" means a single electronic message a User submits to the Exchange in which the User may enter, modify, or cancel up to an Exchange-specified number of bids and offers. Upon migration the System will handle a bulk message bid or offer in the same manner as it handles an order or quote, unless the Rules specify otherwise. The proposed rule change accounts for bulk message functionality and makes explicit the price protections that will not apply to such messages. This is consistent with C2 Rule 6.14.

⁸ Rule to be effective on October 7, 2019 and governs the operation of the Exchange's Public Automated Routing System ("PAR").

current debit/credit reasonability check, with respect to pairs with different expiration the System pairs of calls (puts) with different expiration dates if the exercise price for the call (put) with the farther expiration date is lower (higher) than the exercise price for the nearer expiration date in addition to those with different expiration dates and the same exercise price. The proposed rule change amends this check to pair orders in the same manner as C2 and EDGX, which is to pair calls (puts) if they have the same expiration date but different exercise prices or the same exercise price but different expiration dates. Additionally, the proposed rule change deletes the exception for complex orders with European-style exercise. This aligns with the corresponding rules of C2 and EDGX and the Exchange no longer believes this exception is necessary and will expand this check to index options with all exercise styles.

The proposed Risk Monitor Mechanism is identical to the current functionality on C2 and substantively the same as the functionality currently available on EDGX. Because there will no longer be separate order and quote functionality on the Exchange following the technology migration, there will no longer be separate mechanisms to monitor entry and execution rates, as there are on the Exchange today. Each User may establish limits for the following parameters in the Exchange's counting program. The System counts each of the following within a class ("class limit")¹⁰ and across all classes for an EFID¹¹ ("firm limit") and/or across all classes for a group of EFIDs ("EFID Group") ("EFID Group limit") over a User-established time period ("interval") on an absolute basis for a trading day ("absolute limits"):

- (i) Number of contracts executed ("volume");
- (ii) notional value of executions ("notional");
- (iii) number of executions ("count");
- (iv) number of contracts executed as a percentage of number of contracts outstanding within an Exchange-designated time period or during the trading day, as applicable ("percentage"), which the System determines by calculating the percentage of a User's outstanding contracts that executed on each side of

the market during the time period or trading day, as applicable, and then summing the series percentages on each side in the class; and

(v) number of times the limits established by the parameters under the above-listed are reached ("risk trips").

Also, when the System determines the volume, notional, count, percentage, or risk trips limits have been reached:

(i) a User's class limit within the interval or the absolute limit for the class, the Risk Monitor Mechanism cancels or rejects such User's orders or quotes in all series of the class and cancels or rejects any additional orders or quotes from the User in the class until the counting program resets (as described below).

(ii) a User's firm limit within the interval or the absolute limit for the firm, the Risk Monitor Mechanism cancels or rejects such User's orders or quotes in all classes and cancels or rejects any additional orders or quotes from the User in all classes until the counting program resets (as described below).

(iii) a User's EFID Group limit within the interval or the absolute limit for the EFID Group, the Risk Monitor Mechanism cancels or rejects such User's orders or quotes in all classes and cancels or rejects any additional orders or quotes from any EFID within the EFID Group in all classes until the counting program resets (as described below).

The Risk Monitor Mechanism will also attempt to cancel or reject any orders routed away to other exchanges. The System processes messages in the order in which they are received. Therefore, it will execute any marketable orders or quotes that are executable against a User's order or quote and received by the System prior to the time the Risk Monitor Mechanism is triggered at the price up to the size of the User's order or quote, even if such execution results in executions in excess of the User's parameters. The System will not accept new orders or quotes from a User after a class limit is reached until the User submits an electronic instruction to the System to reset the counting program for the class. The System will not accept new orders or quotes from a User after an EFID limit or EFID Group limit is reached until the User manually notifies the Trade Desk to reset the counting program for the firm, unless the User instructs the Exchange to permit it to reset the counting program by submitting an electronic message to the System. The Exchange may restrict the number of User class and firm resets per second. The System counts executed COA

responses as part of the Risk Monitor Mechanism. The System counts individual trades executed as part of a complex order when determining whether the volume, notional, count, or risk trips limit has been reached. The System counts the percentage executed of a complex order when determining whether the percentage limit has been reached. In addition, a User may also engage the Risk Monitor Mechanism to cancel resting bids and offers, as well as order set forth in the kill switch protection provision. The Risk Monitor Mechanism provides Users with similar ability to manage their order and execution risk to the quote risk monitor and rate checks currently available on the Exchange, and merely uses different parameters and modifies the functionality to conform the new System to that of C2 and EDGX upon migration.

With respect to various price protections and risk controls in current Rules 6.12.01, 6.13, and 6.53C.08, the Exchange has the authority to provide intraday relief by widening or inactivating one or more of the parameter settings for the mechanisms in those rules. This authority is included in proposed Interpretation and Policy .01, to provide this flexibility for all price protections and risk controls for which the Exchange sets parameters, providing the Exchange with flexibility it believes appropriate given previous experience with risk controls. This is consistent with corresponding C2 Rule 6.14.01. The Exchange will continue to make and keep records to document all determinations to grant intraday relief, and periodically review these determinations for consistency with the interest of a fair and orderly market.

The proposed rule change makes a non-substantive change in moving the provision regarding the Exchange's ability to share User-designated risk settings in the System with a Clearing Trading Permit Holder that clears Exchange transactions on behalf of the User from the introduction of current Rule 6.14 to proposed Rule 5.34.02. Also, the proposed change makes non-substantive changes in that it updates all provisions to account for "User" as opposed to Trading Permit Holder ("TPH"), which is consistent with the definition under Rule 1.1 the shell Rulebook, and the use of the term throughout the Exchange Rules upon migration.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations

¹⁰ The Exchange also changes the term "underlying" and "underlying limit" currently in the C2 rule to "class" and "class limit" which more accurately reflect this Risk Monitor Mechanism limit and the language in the current Exchange rule.

¹¹ The Exchange will use EFIDs (*i.e.*, Executing Firm IDs) upon migration. See Rule 1.1 in the shell Rulebook.

thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.¹² Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹³ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁴ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The proposed rule change is generally intended to add or align certain System functionality in connection with price protection mechanisms and risk controls with functionality currently offered by C2 and EDGX in order to provide a consistent technology offering for the Cboe Affiliated Exchanges. A consistent technology offering, in turn, will simplify the technology implementation, changes and maintenance by Users of the Exchange that are also participants on Cboe Affiliated Exchanges. The proposed rule changes would also provide Users with access to functionality that is generally available on markets other than the Cboe Affiliated Exchanges and may result in the efficient execution of such orders and will provide additional flexibility as well as increased functionality to the Exchange's System and its Users. The proposed rule change seeks to provide greater harmonization between the rules of the Cboe Affiliated Exchanges, which would result in greater uniformity and less burdensome and more efficient regulatory compliance. As such, the proposed rule change would foster cooperation and coordination with persons engaged in facilitating transactions in securities and would remove impediments to and perfect the mechanism of a free and open market and a national market system. The Exchange also believes that consistent rules will increase the understanding of the Exchange's operations for Trading Permit Holders that are also participants on the Cboe

Affiliated Exchanges, thereby contributing to the protection of investors and the public interest. The proposed rule change does not propose to implement new or unique functionality that has not been previously filed with the Commission or is not available on Cboe Affiliated Exchanges. The Exchange notes that the proposed rule text mirrors C2 Rules, save for intended differences that account for PAR (unique to the Exchange), Exchange-specific cross-references and references to certain terms (*i.e.* User throughout the proposed rule).

Overall, the Exchange believes the additional and enhanced price protection mechanisms and risk controls will protect investors and the public interest and maintain fair and orderly markets by mitigating potential risks associated with market participants entering orders and quotes at unintended prices, and risks associated with orders and quotes trading at prices that are extreme and potentially erroneous, which may likely have resulted from human or operational error. The Exchange notes that the proposed rule change is substantially similar to the current Cboe Options Rules, and, while the Exchange currently offers many similar protections and controls, as described above, the Exchange believes Users will benefit from the additional functionality that will be available following the technology migration.

As indicated in the table above, the proposed price protection and risk control mechanisms no longer establish outer boundaries or limits to the levels at which mechanisms are set (save for the proposed no-bid provision, noted below), but instead, the proposed rule change amends the price protection mechanisms and risk controls to account for Exchange-determined and/or User-determined buffer or default amounts. The Exchange believes this removes impediments to and perfects the mechanism of a free and open market and national market system because it affords the Exchange and Users reasonable and necessary flexibility to establish and modify the default parameters, which, in turn, protects investors and the public interest, and maintains a fair and orderly market. The Exchange notes any Exchange-determined parameters will always be available on the Exchange's website via specification or Notice.¹⁵ The Exchange also believes the proposed rule change to the no-bid provisions, that the System cancels or

rejects a market order if there is no-bid and the best offer is less than or equal to \$0.50, as well as a market order where there is no-offer, is designed to protect User's as it will provide protection for market orders to prevent execution at potentially erroneous prices when a market order is entered in a series with no bid or offer.

The proposed drill-through protections for complex orders removes impediments to and perfect the mechanism of a free and open market and national market system and facilitates transactions in securities by adding detail to the rules regarding complex order price protections. Particularly, by adding that a COA-eligible order would initiate a COA at the drill-through price because the prices for complex strategy executions may be subject to the drill-through protection and permitting an order that is not currently executable due to Legging restrictions to remain on the COB if the SBBO changes during the set time-period will provide additional execution opportunities, for Users' orders participating in the COA and/or prior to cancellation.

The proposed provision in connection with the Risk Monitor Mechanism will not alter the function of this mechanism for market participants as it provides Users with the ability to manage their order and execution risk to the quote risk monitor and rate checks similar to that which is currently available on the Exchange, and merely uses different parameters and modifies the functionality to conform the new System to that of C2 and EDGX upon migration. The Exchange also notes that this functionality is optional; it is User-enabled and the parameters are User-established.

The proposed rule change also removes functionality, and reference to such functionality, that will not exist upon migration in order to align the Exchange's System with that of its affiliated options exchanges, which will serve to remove impediments to and perfect the mechanism of a free and open market and national market system by providing market participants with rules that accurately reflect functionality post-migration and effectively harmonize Exchange functionality with that of C2 and EDGX. Moreover, the Exchange does not believe that the proposed change that removes functionality that will no longer be available upon migration will impact investors because the proposed change provides substantially similar alternative mechanisms and controls that result in the same protections as current Exchange functionality. The

¹² 15 U.S.C. 78f(b).

¹³ 15 U.S.C. 78f(b)(5).

¹⁴ *Id.*

¹⁵ See Rule 1.5 in the shell Rulebook.

Exchange believes that the proposed rule provides a full suite of price protection mechanisms and risk controls, the same as those currently in effect on its affiliated options exchanges, which will sufficiently mitigate risks associated with market participants entering orders and quotes at unintended prices, and risks associated with orders and quotes trading at prices that are extreme and potentially erroneous, as a likely result of human or operational error. The Exchange also notes that a majority of the proposed price protection mechanisms and risks controls are voluntary and/or User-determined, which benefits market participants by providing Users with additional control and flexibility in connection with their orders.

As stated, the Exchange notes the proposed price protection mechanisms and risk controls provisions do not present any new or unique rules or functionality for market participants as the proposed rule is substantially similar to the Exchange's current rules, identical to C2 Rule 6.14, as well as substantively the same as corresponding EDGX rules and technical specifications, as discussed above. The proposed rule change makes various non-substantive changes throughout the rules by updating cross-references and Exchange-specific terms, and by means of conforming language to C2 Rule 6.14, as well as corresponding EDGX rules, that will protect investors and benefit market participants as these changes simplify or clarify rules, delete duplicative rule provisions, conform paragraph numbering and lettering throughout the rules, and use plain English.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange reiterates that the proposed rule change is being proposed in the context of the technology integration of the Cboe Affiliated Exchanges. Thus, the Exchange believes this proposed rule change is necessary to permit fair competition among national securities exchanges.

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the proposed rule change is designed to benefit Exchange participants in that it will provide a

consistent technology offering for Users by the Cboe Affiliated Exchanges. Following the technology migration, the Exchange's System, as described in this proposed rule change, will apply to all Users and order and quotes submitted by Users in the same manner. The Exchange also notes that many of the proposed price protections and risk controls are either User-determined or altogether voluntary.

In addition to this, the Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the basis for the majority of the proposed rule changes in this filing are the rules of C2 and EDGX, which have previously been filed with the Commission. The Exchange also notes that market participants on other exchanges are welcome to become participants on the Exchange if they determine that this proposed rule change has made Cboe Options a more attractive or favorable venue. As stated, the proposed changes to the rules that accurately reflect functionality that will be in place come October 7, 2019, will not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act but rather provide clear, consistent rules for market participants surrounding the completion of migration.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁶ and paragraph (f) of Rule 19b-4¹⁷ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule

change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-CBOE-2019-057 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-CBOE-2019-057. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of 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-CBOE-2019-057, and should be submitted on or before October 7, 2019.

¹⁶ 15 U.S.C. 78s(b)(3)(A).

¹⁷ 17 CFR 240.19b-4(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019-19902 Filed 9-13-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Investment Company Act Release No. 33622; File No. 812-15031 ETFis Series Trust I, et al.; Notice of Application

September 11, 2019.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice.

Notice of an application for an order under section 12(d)(1)(f) of the Investment Company Act of 1940 (the "Act") for an exemption from sections 12(d)(1)(A), (B), and (C) of the Act and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and (2) of the Act. The requested order would permit certain registered open-end investment companies to acquire shares of certain registered open-end investment companies (each an "Unaffiliated Open-End Investment Company"), registered closed-end investment companies and "business development companies," as defined in section 2(a)(48) of the Act (each registered closed-end management and each business development company, an "Unaffiliated Closed-End Investment Company" and, together with the Unaffiliated Open-End Investment Companies, the "Unaffiliated Investment Companies"), and registered unit investment trusts (the "Unaffiliated Trusts," and together with the Unaffiliated Investment Companies, the "Unaffiliated Funds") that are within the same group of investment companies (collectively, the "Affiliated Funds") and outside the same group of investment companies (collectively, the "Unaffiliated Funds"), in excess of the limits in section 12(d)(1) of the Act.

APPLICANTS: ETFis Series Trust I and Virtus ETF Trust II, Delaware statutory trusts that are registered under the Act as open-end management investment companies and intend to introduce multiple series, and Virtus ETF Advisers LLC, a Delaware limited liability company registered as an

investment adviser under the Investment Advisers Act of 1940.

FILING DATES: The application was filed on May 9, 2019.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on October 7, 2019 and should be accompanied by proof of service on the applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to Rule 0-5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. Applicants: William J. Smalley, Virtus ETF Advisers LLC, 1540 Broadway, New York, NY 10036; and Michael W. Mundt, Esq., Stradley Ronon Stevens & Young, LLP, 1250 Connecticut Avenue NW, Suite 500, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Rochelle Kauffman Plesset, Senior Counsel, or David J. Marcinkus, Branch Chief, at (202) 551-6825, (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at <http://www.sec.gov/search/search.htm>, or by calling (202) 551-8090.

Summary of the Application

1. Applicants request an order to permit (a) a Fund¹ (each a "Fund of

¹ Applicants request that the order apply to each existing and future series of ETFis Series Trust I and Virtus ETF Trust II and to each existing and future registered open-end investment company or series thereof that is advised by Virtus ETF Advisers LLC or its successor or by any other investment adviser controlling, controlled by or under common control with Virtus ETF Advisers LLC or its successor and is part of the same "group of investment companies" as ETFis Series Trust I and Virtus ETF Trust II (each, a "Fund"). For purposes of the requested order, "successor" is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization. For purposes of the request for relief, the term "group of

Funds") to acquire shares of Underlying Funds² in excess of the limits in sections 12(d)(1)(A) and (C) of the Act and (b) the Underlying Funds that are registered open-end investment companies or series thereof, their principal underwriters and any broker or dealer registered under the Securities Exchange Act of 1934 to sell shares of the Underlying Fund to the Fund of Funds in excess of the limits in section 12(d)(1)(B) of the Act.³ Applicants also request an order of exemption under sections 6(c) and 17(b) of the Act from the prohibition on certain affiliated transactions in section 17(a) of the Act to the extent necessary to permit the Underlying Funds to sell their shares to, and redeem their shares from, the Funds of Funds.⁴ Applicants state that such transactions will be consistent with the policies of each Fund of Funds and each Underlying Fund and with the general purposes of the Act and will be based on the net asset values of the Underlying Funds.

2. Applicants agree that any order granting the requested relief will be subject to the terms and conditions stated in the application. Such terms and conditions are designed to, among other things, help prevent any potential

investment companies" means any two or more registered investment companies, including closed-end investment companies and business development companies, that hold themselves out to investors as related companies for purposes of investment and investor services.

² Certain of the Underlying Funds have obtained exemptions from the Commission necessary to permit their shares to be listed and traded on a national securities exchange at negotiated prices and, accordingly, to operate as an exchange-traded fund ("ETF").

³ Applicants do not request relief for Funds of Funds to invest in reliance on the order in business development companies and registered closed-end investment companies that are not listed and traded on a national securities exchange.

⁴ A Fund of Funds generally would purchase and sell shares of an Underlying Fund that operates as an ETF or closed-end fund through secondary market transactions rather than through principal transactions with the Underlying Fund. Applicants nevertheless request relief from sections 17(a)(1) and (2) to permit each ETF or Unaffiliated Closed-End Investment Company that is an affiliated person, or an affiliated person of an affiliated person, as defined in section 2(a)(3) of the 1940 Act, of a Fund of Funds to sell shares to or redeem shares from the Fund of Funds. This includes, in the case of sales and redemptions of shares of ETFs, the in-kind transactions that accompany such sales and redemptions. The Applicants are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where an ETF, business development company, or closed-end fund could be deemed an affiliated person, or an affiliated person of an affiliated person, of a Fund of Funds because an investment adviser to the ETF, business development company, or closed-end fund or an entity controlling, controlled by or under common control with the investment adviser to the ETF, business development company, or closed-end fund, is also an investment adviser to the Fund of Funds.

¹⁸ 17 CFR 200.30-3(a)(12).

(i) undue influence over an Underlying Fund that is not in the same “group of investment companies” as the Fund of Funds through control or voting power, or in connection with certain services, transactions, and underwritings, (ii) excessive layering of fees, and (iii) overly complex fund structures, which are the concerns underlying the limits in sections 12(d)(1)(A), (B), and (C) of the Act.

3. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Section 17(b) of the Act authorizes the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if it finds that (a) the terms of the proposed transaction are fair and reasonable and do not involve overreaching on the part of any person concerned; (b) the proposed transaction is consistent with the policies of each registered investment company involved; and (c) the proposed transaction is consistent with the general purposes of the Act. Section 6(c) of the Act permits the Commission to exempt any persons or transactions from any provision of the Act if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–19979 Filed 9–13–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, the Securities and Exchange Commission will hold an Open Meeting on Wednesday, September 18, 2019 at 10:00 a.m.

PLACE: The meeting will be held in Auditorium LL–002 at the Commission’s headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will begin at 10:00 a.m. (ET) and will be open to the public.

Seating will be on a first-come, first-served basis. Visitors will be subject to security checks. The meeting will be webcast on the Commission’s website at www.sec.gov.

MATTER TO BE CONSIDERED: 1. The Commission will consider whether to adopt amendments to rules adopted under section 13 of the Bank Holding Company Act related to prohibitions and restrictions on proprietary trading and certain interests in, and relationships with, hedge funds and private equity funds (commonly known as the “Volcker rule”).

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

CONTACT PERSON FOR MORE INFORMATION:

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact Vanessa A. Countryman, Office of the Secretary, at (202) 551–5400.

Dated: September 11, 2019.

Vanessa A. Countryman,
Secretary.

[FR Doc. 2019–20040 Filed 9–12–19; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86917; File No. SR–NYSEAMER–2019–36]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE American Options Fee Schedule

September 10, 2019.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (the “Act”) ² and Rule 19b–4 thereunder, ³ notice is hereby given that, on September 3, 2019, NYSE American LLC (“NYSE American” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 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 the NYSE American Options Fee Schedule (“Fee Schedule”). The Exchange proposes to implement the fee change effective September 3, 2019. The proposed change is available on the Exchange’s website at www.nyse.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to amend the Fee Schedule to modify the Strategy Execution Fee Cap (“Strategy Cap”), as set forth below.

Currently, Section I.J. of the Fee Schedule provides that transaction fees for ATP Holders are limited or capped at \$750 for certain options strategy executions “on the same trading day in the same option class” and such fees are further capped at \$25,000 per month per initiating firm.⁴ Strategy executions that qualify for the Strategy Cap are (a) reversals and conversions, (b) box spreads, (c) short stock interest spreads, (d) merger spreads, and (e) jelly rolls, which are described in detail in the Fee Schedule (the “Strategy Executions”).⁵

The Exchange proposes to increase the daily Strategy Cap from \$750 to \$1,000 and to include in the Cap all Strategy Executions traded in the same day (*i.e.*, to eliminate the Cap requirement that strategies be in the

⁴ See Fee Schedule, Section I. J. (Strategy Execution Fee Cap), available here: https://www.nyse.com/publicdocs/nyse/markets/american-options/NYSE_American_Options_Fee_Schedule.pdf.

⁵ See *id.* Any qualifying Strategy Execution executed as a QCC order will not be eligible for this fee cap. See *id.*

same option class). In connection with this change, the Exchange proposes to eliminate the \$25,000 monthly Strategy Cap. The Exchange believes that the proposed Strategy Cap would encourage ATP Holders to execute more Strategy Executions, particularly those that would not individually qualify for inclusion in the Cap because of the current per-symbol limitation, as such strategies would become more economically feasible (and thus more attractive), when combined under the proposed Cap with all of an ATP Holder's Strategy Executions on the same trading day.

The Exchange proposes to implement the rule change on September 3, 2019.

Background

The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system "has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies."⁶

There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.⁷ Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity & ETF options order flow. More specifically, in the first quarter of 2019, the Exchange had less than 10% market share of executed volume of multiply-listed equity & ETF options trades.⁸

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces

constrain options exchange transaction fees.

In response to this competitive environment, the Exchange has established incentives, such as the Strategy Cap, to encourage ATP Holders to participate in certain large volume options strategies that capture potentially small profits by capping the fees paid for such transactions.

As noted above, the current Strategy Cap limits or caps at \$750 transaction fees for options Strategy Executions "on the same trading day in the same option class" and further caps such fees at \$25,000 per month.⁹

Proposed Rule Change

The Exchange proposes to modify the Strategy Cap by eliminating the requirement that Strategy Executions on the same trading day all be in the same symbol for inclusion in the Cap. Specifically, as proposed, the daily Strategy Cap on transaction fees for options Strategy Executions would be changed from \$750 to \$1,000 and would apply to all Strategy Executions by an ATP Holder on the same trading day (regardless of option class/symbol). In addition, given the proposal to cap an ATP Holder's fee for all Strategy Executions in a given trading day at \$1,000, the Exchange proposed to eliminate the \$25,000 per month Strategy Cap as unnecessary.

For example, per the current Fee Schedule, an ATP Holder that executes the following Strategy Executions on the same trading day would be charged as follows:

- A Jelly Roll in ABC for \$800 in fees, capped at \$750;
- A Reversal Conversion in DEF for \$500 in fees; and
- A Merger Spread in XYZ for \$600.

The total fees for these Strategy Executions under the current Fee Schedule would be \$1,850. Under the proposed Strategy Cap, the same trades would be billed as follows:

- A Jelly Roll in ABC for \$800 in fees;
- A Reversal Conversion in DEF for \$500 in fees; and
- A Merger Spread in XYZ for \$600.

The total fees for these Strategy Executions under the proposed Fee Schedule would be \$1,000. Thus, although the amount of the Cap would be increased, the number of eligible Strategy Executions would also be increased, making it easier to meet the Strategy Cap.

The Exchange's fees are constrained by intermarket competition, as ATP Holders may direct their order flow to

any of the 16 options exchanges, including those with similar Strategy Fee Caps.¹⁰ Thus, ATP Holders have a choice of where they direct their order flow. This proposed change is designed to incent ATP Holders to increase their Strategy Execution volumes by executing (often smaller) strategies that are not necessarily economically viable on a per symbol basis, but which may be profitable when fees on Strategy Executions—regardless of symbol—are capped for the trading day. The Exchange notes that all market participants stand to benefit from increased volume, which promotes market depth, facilitates tighter spreads and enhances price discovery, and may lead to a corresponding increase in order flow from other market participants.

The Exchange cannot predict with certainty whether any ATP Holders would avail themselves of this proposed fee change. At present, whether or when an ATP Holder qualifies for the current daily Strategy Cap (of \$750) varies day-to-day in a given month. Thus, the Exchange cannot predict with any certainty the number of ATP Holders that may qualify for the modified Strategy Cap, but believes that ATP Holders would be encouraged to take advantage of the modified Cap. The Exchange believes the proposed Strategy Cap, which applies to all qualifying strategies executed on the same trading day, regardless of symbol, would provide an incentive for ATP Holders to submit these types of strategy orders to the Exchange Trading Floor, which brings increased liquidity and order flow for the benefit of all market participants.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,¹¹ in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,¹² in particular, because it provides for the equitable

¹⁰ See e.g., BOX Options Market LLC ("BOX") fee schedule, Section II.D (Strategy QOO Order Fee Cap and Rebate). BOX caps fees for each participants at \$1,000 for the following strategies executed on the same trading day: short stock interest, [sic], reversal, conversion, jelly roll, and box spread strategies. BOX also caps participant fees at \$1,000 for all dividend strategies executed on the same trading day in the same options class. BOX also offers a \$500 rebate to floor brokers for presenting certain Strategy QOO Orders on the BOX trading floor, which is applied "once the \$1,000 fee cap for all dividend, short stock interest, merger, reversal, conversion, jelly roll, and box spread strategies is met." See *id.* The Exchange does not include dividend strategies in the Strategy Cap, nor does the Exchange does not offer a similar rebate.

¹¹ 15 U.S.C. 78f(b).

¹² 15 U.S.C. 78f(b)(4) and (5).

⁶ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7-10-04) ("Reg NMS Adopting Release").

⁷ The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: <https://www.theocc.com/market-data/volume/default.jsp>.

⁸ Based on OCC data, see *id.*, the Exchange's market share in equity-based options declined from 9.82% for the month of January to 8.84% for the month of April.

⁹ See Fee Schedule, Section I. J. (Strategy Execution Fee Cap), *supra* note 4.

allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Rule Change Is Reasonable

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system “has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.”¹³

There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.¹⁴ Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity & ETF options order flow. More specifically, in the first quarter of 2019, the Exchange had less than 10% market share of executed volume of multiply-listed equity & ETF options trades.¹⁵

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain options exchange transaction fees. Stated otherwise, changes to exchange transaction fees can have a direct effect on the ability of an exchange to compete for order flow.

The Exchange believes that the proposed modification to the Strategy Cap is designed to incent ATP Holders to increase the number and type of Strategy Executions sent to the Exchange. In addition, the proposal caps fees on all similar transactions, regardless of size and similarly-situated ATP Holders can opt to try to achieve

the modified Strategy Cap. The proposal is designed to encourage ATP Holders to send all Strategy Executions to the Exchange regardless of size or type. To the extent that the proposed change attracts more Strategy Executions to the Exchange Trading Floor, this increased order flow would continue to make the Exchange a more competitive venue for, among other things, order execution, which, in turn, promotes just and equitable principles of trade and removes impediments to and perfects the mechanism of a free and open market and a national market system.

Finally, to the extent the proposed change continues to attract greater volume and liquidity (to the Floor or otherwise), the Exchange believes the proposed change would improve the Exchange’s overall competitiveness and strengthen its market quality for all market participants. In the backdrop of the competitive environment in which the Exchange operates, the proposed rule change is a reasonable attempt by the Exchange to increase the depth of its market and improve its market share relative to its competitors. The Exchange’s fees are constrained by intermarket competition, as ATP Holders may direct their order flow to any of the 16 options exchanges, including those with similar Strategy Fee Caps.¹⁶ Thus, ATP Holders have a choice of where they direct their order flow—including their Strategy Executions. The proposed rule change is designed to incent ATP Holders to direct liquidity to the Exchange—in particular Strategy Executions, thereby promoting market depth, price discovery and improvement and enhancing order execution opportunities for market participants.

The Exchange cannot predict with certainty whether any ATP Holders would avail themselves of this proposed fee change. At present, whether or when an ATP Holder qualifies for the current daily Strategy Cap (of \$750) varies day-to-day in a given month. Thus, the Exchange cannot predict with any certainty the number of ATP Holders that may qualify for the modified Strategy Cap, but believes that ATP Holders would be encouraged to take advantage of the modified Cap. The Exchange believes the proposed Strategy Cap, which applies to all qualifying strategies executed on the same trading day, regardless of symbol, would provide an incentive for ATP Holders to submit these types of strategy orders to the Exchange Trading Floor, which brings increased liquidity and order

flow for the benefit of all market participants.

The Proposed Rule Change Is an Equitable Allocation of Credits and Fees

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits. The proposal is based on the amount and type of business transacted on the Exchange and ATP Holders can opt to avail themselves of the Strategy Cap or not. Moreover, the proposal is designed to encourage ATP Holders to aggregate all Strategy Executions at the Exchange as a primary execution venue. To the extent that the proposed change attracts more Strategy Executions to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for, among other things, order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange thereby improving market-wide quality and price discovery.

The Proposed Rule Change Is Not Unfairly Discriminatory

The Exchange believes it is not unfairly discriminatory to modify the Strategy Cap because the proposed modification would be available to all similarly-situated market participants on an equal and non-discriminatory basis.

The proposal is based on the amount and type of business transacted on the Exchange and ATP Holders are not obligated to try to achieve the Strategy Cap. Rather, the proposal is designed encourage ATP Holders to utilize the Exchange as a primary trading venue for Strategy Executions (if they have not done so previously) or increase volume sent to the Exchange. To the extent that the proposed change attracts more Strategy Executions to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for, among other things, order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange thereby improving market-wide quality and price discovery. The resulting increased volume and liquidity would provide more trading opportunities and tighter spreads to all market participants and thus would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market

¹³ See Reg NMS Adopting Release, *supra* note 6, at 37499.

¹⁴ See *supra* note 7.

¹⁵ Based on OCC data, see *supra* note 8, in 2019, the Exchange’s market share in equity-based options declined from 9.82% for the month of January to 8.84% for the month of April.

¹⁶ See *supra* note 10 (regarding BOX Strategy Cap).

and a national market system and, in general, to protect investors and the public interest.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all market participants. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes "more efficient pricing of individual stocks for all types of orders, large and small."¹⁷

Intramarket Competition. The proposed change is designed to attract additional order flow (particularly Strategy Executions) to the Exchange. The Exchange believes that the proposed Strategy Cap would incent market participants to direct their Strategy Execution volume to the Exchange. Greater liquidity benefits all market participants on the Exchange and increased Strategy Executions would increase opportunities for execution of other trading interest. The proposed Strategy Cap would be available to all similarly-situated market participants that incur transaction fees on Strategy Executions, and, as such, the proposed change would not impose a disparate burden on competition among market participants on the Exchange.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily favor one of the 16 competing option exchanges if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other

exchanges and to attract order flow to the Exchange. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.¹⁸ Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity & ETF options order flow. More specifically, in the first quarter of 2019, the Exchange had less than 10% market share of executed volume of multiply-listed equity & ETF options trades.¹⁹

The Exchange believes that the proposed rule change reflects this competitive environment because it modifies the Exchange's fees in a manner designed to encourage ATP Holders to direct trading interest (particularly Strategy Executions) to the Exchange, to provide liquidity and to attract order flow. To the extent that this purpose is achieved, all the Exchange's market participants should benefit from the improved market quality and increased opportunities for price improvement.

The Exchange believes that the proposed change could promote competition between the Exchange and other execution venues, including those that currently offer similar Strategy Caps, by encouraging additional orders to be sent to the Exchange for execution. The Exchange also believes that the proposed change is designed to provide the public and investors with a Fee Schedule that is clear and consistent, thereby reducing burdens on the marketplace and facilitating investor protection.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)²⁰ of the Act and subparagraph (f)(2) of Rule 19b-4²¹ thereunder, because it establishes a due,

fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)²² of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File No. SR-NYSEAMER-2019-36 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 No. SR-NYSEAMER-2019-36. 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

¹⁷ See Reg NMS Adopting Release, *supra* note 6, at 37499.

¹⁸ See *supra* note 7.

¹⁹ Based on OCC data, *supra* note 8, the Exchange's market share in equity-based options declined from 9.82% for the month of January to 8.84% for the month of April.

²⁰ 15 U.S.C. 78s(b)(3)(A).

²¹ 17 CFR 240.19b-4(f)(2).

²² 15 U.S.C. 78s(b)(2)(B).

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 No. SR-NYSEAMER-2019-36, and should be submitted on or before October 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²³

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019-19905 Filed 9-13-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Extension:

Rule 7d-2, SEC File No. 270-464, OMB Control No. 3235-0527

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520), the Securities and Exchange Commission (the "Commission") has submitted to the Office of Management and Budget a request for extension and approval of the collection of information discussed below.

In Canada, as in the United States, individuals can invest a portion of their earnings in tax-deferred retirement savings accounts ("Canadian retirement accounts"). These accounts, which operate in a manner similar to individual retirement accounts in the United States, encourage retirement savings by permitting savings on a tax-deferred basis. Individuals who establish Canadian retirement accounts while living and working in Canada and who later move to the United States ("Canadian-U.S. Participants" or "participants") often continue to hold their retirement assets in their Canadian retirement accounts rather than prematurely withdrawing (or "cashing out") those assets, which would result in immediate taxation in Canada.

Once in the United States, however, these participants historically have been unable to manage their Canadian retirement account investments. Most investment companies ("funds") that are "qualified companies" for Canadian retirement accounts are not registered under the U.S. securities laws. Securities of those unregistered funds, therefore, generally cannot be publicly offered and sold in the United States without violating the registration requirement of the Investment Company Act of 1940 ("Investment Company Act").¹ As a result of this registration requirement, Canadian-U.S. Participants previously were not able to purchase or exchange securities for their Canadian retirement accounts as needed to meet their changing investment goals or income needs.

The Commission issued a rulemaking in 2000 that enabled Canadian-U.S. Participants to manage the assets in their Canadian retirement accounts by providing relief from the U.S. registration requirements for offers of securities of foreign issuers to Canadian-U.S. Participants and sales to Canadian retirement accounts.² Rule 7d-2 under the Investment Company Act³ permits foreign funds to offer securities to Canadian-U.S. Participants and sell securities to Canadian retirement accounts without registering as investment companies under the Investment Company Act.

Rule 7d-2 contains a "collection of information" requirement within the meaning of the Paperwork Reduction Act of 1995.⁴ Rule 7d-2 requires written offering materials for securities offered or sold in reliance on that rule to disclose prominently that those securities and the fund issuing those securities are not registered with the Commission, and that those securities and the fund issuing those securities are exempt from registration under U.S. securities laws. Rule 7d-2 does not require any documents to be filed with the Commission.

Rule 7d-2 requires written offering documents for securities offered or sold

in reliance on the rule to disclose prominently that the securities are not registered with the Commission and may not be offered or sold in the United States unless registered or exempt from registration under the U.S. securities laws, and also to disclose prominently that the fund that issued the securities is not registered with the Commission. The burden under the rule associated with adding this disclosure to written offering documents is minimal and is non-recurring. The foreign issuer, underwriter, or broker-dealer can redraft an existing prospectus or other written offering material to add this disclosure statement, or may draft a sticker or supplement containing this disclosure to be added to existing offering materials. In either case, based on discussions with representatives of the Canadian fund industry, the staff estimates that it would take an average of 10 minutes per document to draft the requisite disclosure statement.

The staff estimates that there are 4,086 publicly offered Canadian funds that potentially would rely on the rule to offer securities to participants and sell securities to their Canadian retirement accounts without registering under the Investment Company Act.⁵ The staff estimates that all of these funds have previously relied upon the rule and have already made the one-time change to their offering documents required to rely on the rule. The staff estimates that 204 (5 percent) additional Canadian funds would newly rely on the rule each year to offer securities to Canadian-U.S. Participants and sell securities to their Canadian retirement accounts, thus incurring the paperwork burden required under the rule. The staff estimates that each of those funds, on average, distributes 3 different written offering documents concerning those securities, for a total of 612 offering documents. The staff therefore estimates that 204 respondents would make 612 responses by adding the new disclosure statement to 612 written offering documents. The staff therefore estimates that the annual burden associated with the rule 7d-2 disclosure requirement would be 102 hours (612 offering documents × 10 minutes per document). The total annual cost of these burden hours is estimated to be \$42,330 (102 hours × \$415 per hour of attorney time).⁶

⁵ Investment Company Institute, 2019 Investment Company Fact Book (2019) at 258, tbl. 66.

⁶ The Commission's estimate concerning the wage rate for attorney time is based on salary information for the securities industry compiled by the Securities Industry and Financial Markets Association ("SIFMA"). The \$380 per hour figure for an attorney is from SIFMA's *Management &*

¹ 15 U.S.C. 80a. In addition, the offering and selling of securities that are not registered pursuant to the Securities Act of 1933 ("Securities Act") is generally prohibited by U.S. securities laws. 15 U.S.C. 77.

² See Offer and Sale of Securities to Canadian Tax-Deferred Retirement Savings Accounts, Release Nos. 33-7860, 34-42905, IC-24491 (June 7, 2000) [65 FR 37672 (June 15, 2000)]. This rulemaking also included new rule 237 under the Securities Act, permitting securities of foreign issuers to be offered to Canadian-U.S. Participants and sold to Canadian retirement accounts without being registered under the Securities Act. 17 CFR 230.237.

³ 17 CFR 270.7d-2.

⁴ 44 U.S.C. 3501-3502.

²³ 17 CFR 200.30-3(a)(12).

These burden hour estimates are based upon the Commission staff's experience and discussions with the fund industry. The estimates of average burden hours are made solely for the purposes of the Paperwork Reduction Act. These estimates are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules.

Compliance with the collection of information requirements of the rule is mandatory and is necessary to comply with the requirements of the rule in general. Responses will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following website, www.reginfo.gov. Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: Lindsay.M.Abate@omb.eop.gov; and (ii) Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549 or send an email to: PRA_Mailbox@sec.gov. Comments must be submitted to OMB within 30 days of this notice.

Dated: September 11, 2019.

Jill M. Peterson,
Assistant Secretary.

[FR Doc. 2019-19973 Filed 9-13-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-86922; File No. SR-NASDAQ-2019-070]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To List and Trade the Common Shares of Beneficial Interest of Invesco BulletShares ETFs

September 10, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934

Professional Earnings in the Securities Industry 2013, modified by Commission staff to account for an 1800-hour work-year and inflation, and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead.

(“Act”)¹ and Rule 19b-4 thereunder,² notice is hereby given that on August 30, 2019, The Nasdaq Stock Market LLC (“Nasdaq” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to list and trade the common shares of beneficial interest of the Invesco BulletShares 2021 Municipal Bond ETF, Invesco BulletShares 2022 Municipal Bond ETF, Invesco BulletShares 2023 Municipal Bond ETF, Invesco BulletShares 2024 Municipal Bond ETF, Invesco BulletShares 2025 Municipal Bond ETF, Invesco BulletShares 2026 Municipal Bond ETF, Invesco BulletShares 2027 Municipal Bond ETF, Invesco BulletShares 2028 Municipal Bond ETF and Invesco BulletShares 2029 Municipal Bond ETF (each a “Fund” or, collectively, the “Funds”), all of which are series of Invesco Exchange-Traded Self-Indexed Fund Trust (the “Trust”), under Nasdaq Rule 5705 (“Rule 5705”). The common shares of beneficial interest of the Funds are referred to herein as the “Shares.”

The text of the proposed rule change is available on the Exchange's website at <http://nasdaq.cchwallstreet.com>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade the Shares under Rule 5705, which rule governs the listing and trading of Index Fund Shares³ on the Exchange.⁴ As discussed below, the Exchange is submitting this proposed rule change because each underlying index that the Funds seek to track (each an “Underlying Index,” and collectively, the “Underlying Indexes”⁵) does not meet all of the “generic” listing requirements of Rule 5705(b)(4) applicable to the listing of Index Fund Shares based on fixed income securities indexes. Each Underlying Index meets all such requirements except for those set forth in Rule 5705(b)(4)(A)(ii).⁶

³ An “Index Fund Share” is a security that is issued by an open-end management investment company based on a portfolio of stocks or fixed income securities or a combination thereof, that seeks to provide investment results that correspond generally to the price and yield performance or total return performance of a specified foreign or domestic stock index, fixed income securities index or combination thereof. See Rule 5705(b)(1)(A).

⁴ The Exchange notes that the Commission has already published immediately effective rule filings allowing the listing and trading of shares of series of Index Fund Shares substantially similar to the Funds. See Securities Exchange Act Release No. 85370 (March 20, 2019), 84 FR 11364 (March 26, 2019) (SR-CboeBZX-2019-017) (Notice of Filing and Immediate Effectiveness of a Proposed Rule to List and Trade Shares of iShares iBonds Dec 2026 Term Muni Bond ETF, iShares iBonds Dec 2027 Term Muni Bond ETF, and iShares iBonds Dec 2028 Term Muni Bond ETF Under BZX Rule 14.11(c)(4)) (the “Comparable Filing”). See also Securities Exchange Act Release No. 84107 (September 13, 2018), 83 FR 47210 (September 18, 2018) (SR-CboeBZX-2018-070). Further, the Commission previously has approved proposed rule changes relating to listing and trading of funds based on municipal bond indexes. See Securities Exchange Act Release No. 79381 (November 22, 2016), 81 FR 86044 (November 29, 2016) (SR-BatsBZX-2016-48) (Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendments No. 1 and No. 2 Thereto, To List and Trade Shares of the iShares iBonds Dec 2023 Term Muni Bond ETF and iShares iBonds Dec 2024 Term Muni Bond ETF of the iShares U.S. ETF Trust Pursuant to BZX Rule 14.11(c)(4)). See also Securities Exchange Act Release No. 78329 (July 14, 2016), 81 FR 47217 (July 20, 2016) (SR-BatsBZX-2016-01) (order approving the listing and trading of the VanEck Vectors AMT-Free 6-8 Year Municipal Index ETF, VanEck Vectors AMT-Free 8-12 Year Municipal Index ETF, and VanEck Vectors AMT-Free 12-17 Year Municipal Index ETF). The Exchange believes the proposed rule change raises no significant issues not previously addressed in those prior Commission orders.

⁵ See “The Funds” below for the list of Underlying Indexes.

⁶ Rule 5705(b)(4)(A)(ii) provides that Fixed Income Components that in aggregate account for at least 75% of the Fixed Income Securities portion of the weight of the index or portfolio each must have

Continued

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

Description of the Shares and the Funds

The Shares will be offered by the respective Funds, each of which will be a passively-managed exchange-traded fund (“ETF”). Each Fund is a series of the Trust. The Trust was established as a Delaware statutory trust on October 30, 2015. The Trust is registered with the Commission as an open-end management investment company and has filed a post-effective amendment to its registration statement on Form N-1A (the “Registration Statement”) with the Commission to register the Funds and their Shares under the Investment Company Act of 1940, as amended, (the “1940 Act”) and the Securities Act of 1933.⁷

Invesco Capital Management LLC will serve as the investment adviser (the “Adviser”) to each Fund. Invesco Distributors, Inc. will serve as the principal underwriter and distributor of the Shares (the “Distributor”). The Bank of New York Mellon will act as the custodian, transfer agent and fund accounting agent for the Funds (the “Custodian”). The Bank of New York Mellon will also serve as the administrator for the Funds (the “Administrator”).

Nasdaq Rule 5705(b)(4)(B)(i) provides that, if an investment company issuing Index Fund Shares tracks an index that is maintained by a broker-dealer or fund advisor, such broker-dealer or fund advisor shall erect and maintain a “fire wall” around the personnel who have access to information concerning

changes and adjustments to the index and the index shall be calculated by a third party who is not a broker-dealer or fund advisor. In addition, Nasdaq Rule 5705 further requires that any advisory committee, supervisory board, or similar entity that makes decisions on the index composition, methodology and related matters, must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material non-public information regarding the applicable index.

The index provider for the Underlying Indexes is Invesco Indexing LLC (the “Index Provider”). The Index Provider is not a broker-dealer or fund advisor, but it is affiliated with the Distributor, a broker-dealer, the Adviser, a fund advisor, and other affiliates that are broker-dealers and fund advisors. The Index Provider has therefore implemented and will maintain a fire wall around the personnel who have access to information concerning changes and adjustments to the Underlying Indexes. In the event a Fund changes its underlying index to an index maintained by a different index provider, such index provider will implement and maintain a fire wall as required. The Index Provider has also implemented policies and procedures designed to prevent the use and dissemination of material non-public information regarding the applicable index by Index Provider personnel that make decisions on each Underlying Index’s composition, methodology and related matters.

Additionally, the calculation agent for each Underlying Index is ICE Data Indices, LLC (“ICE”), a third party who is not a broker-dealer or fund advisor. ICE does not participate in the composition or methodology of the Underlying Indexes.

The Adviser is not a broker-dealer, but is affiliated with a broker-dealer and has implemented and will maintain a “fire wall” with respect to its broker-dealer affiliate regarding access to information concerning the composition and/or changes to each Fund’s portfolio. In the event (a) the Adviser becomes newly affiliated with a different broker-dealer (or becomes a registered broker-dealer itself), or (b) any new adviser or sub-adviser to a Fund is a registered broker-dealer or becomes affiliated with a broker-dealer, each will implement and maintain a fire wall with respect to its relevant personnel and/or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition and/or changes to each Fund’s portfolio and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding each Fund’s portfolio.

The Funds

Each of the Funds will be a passively-managed ETF with investment objective to seek to track the investment results (before fees and expenses) of the following Underlying Indexes.⁸

Fund	Underlying Index
Invesco BulletShares 2021 Municipal Bond ETF	Invesco BulletShares® Municipal Bond 2021 Index (the “2021 Index”).
Invesco BulletShares 2022 Municipal Bond ETF	Invesco BulletShares® Municipal Bond 2022 Index (the “2022 Index”).
Invesco BulletShares 2023 Municipal Bond ETF	Invesco BulletShares® Municipal Bond 2023 Index (the “2023 Index”).
Invesco BulletShares 2024 Municipal Bond ETF	Invesco BulletShares® Municipal Bond 2024 Index (the “2024 Index”).
Invesco BulletShares 2025 Municipal Bond ETF	Invesco BulletShares® Municipal Bond 2025 Index (the “2025 Index”).
Invesco BulletShares 2026 Municipal Bond ETF	Invesco BulletShares® Municipal Bond 2026 Index (the “2026 Index”).
Invesco BulletShares 2027 Municipal Bond ETF	Invesco BulletShares® Municipal Bond 2027 Index (the “2027 Index”).
Invesco BulletShares 2028 Municipal Bond ETF	Invesco BulletShares® Municipal Bond 2028 Index (the “2028 Index”).
Invesco BulletShares 2029 Municipal Bond ETF	Invesco BulletShares® Municipal Bond 2029 Index (the “2029 Index”).

Principal Investments

Each Fund will seek to achieve its investment objective by investing, under normal market conditions,⁹ at least 80%

of its total assets in securities that comprise its Underlying Index (the “Index Tracking Policy”). Each Underlying Index is designed to

measure the performance of a maturity-targeted segment of the investment grade municipal bond market. The Index Provider allocates bonds from a

a minimum original principal amount outstanding of \$100 million or more. As further described herein, due to the nature of municipal bonds and variable rate demand obligation bonds (“VRDOs”), of which the Underlying Indexes are composed, and the way in which they are typically issued, most such instruments do not have original principal amounts outstanding of \$100 million or more.

⁷ See Post-Effective Amendment No. 43 to Registration Statement for the Trust, filed on May 24, 2019 (File Nos. 333-221046 and 811-23304). The descriptions of the Trust, the Funds and the

Shares contained herein are based, in part, on information in the Registration Statement. In addition, the Commission has issued an order granting certain exemptive relief to the Trust under the 1940 Act. See *PowerShares Exchange-Traded Self-Indexed Fund Trust et al.*, SEC Rel. No. IC-31995 (Feb. 11, 2016) (notice); SEC Rel. No. IC-32025 (March 8, 2016) (order) (“Exemptive Order”).

⁸ Unless otherwise noted, all statistics related to the Underlying Indexes presented hereafter were accurate of May 31, 2019.

⁹ The term “normal market conditions” includes, but is not limited to, the absence of trading halts in the applicable financial markets generally; operational issues (e.g., systems failure) causing dissemination of inaccurate market information; or force majeure type events such as natural or manmade disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance.

universe of U.S. dollar-denominated bonds ("Municipal Bonds") issued by U.S. states, state agencies, territories and possessions of the United States, the District of Columbia, or local government¹⁰ meeting certain eligibility criteria into each Underlying Index based on the bond's maturity or, in some cases, effective maturity date.¹¹ Effective maturity is an assessment of a bond's likely call date or maturity (if not called by the issuer). With respect to establishing the effective maturity of a bond, if no embedded issuer call option exists for a bond, then the Index Provider deems effective maturity to be the actual year of maturity. If a bond contains an embedded issuer call option, with the first call date within 13 months of maturity and a par call price, then the Index Provider also deems effective maturity to be the actual year of maturity. In other cases, the Index Provider deems effective maturity to be the actual year of maturity, unless the yield to next call date is less than the yield to maturity, in which case the bond's effective maturity is deemed to be the year of the next call date. The Index Provider deems the effective maturity of eligible pre-refunded Municipal Bonds with a known pre-refunding date as the year of the pre-refunded date.

To be included in the Underlying Indexes, a Municipal Bond must (i) be exempt from federal income tax; (ii) be rated at least BBB- by S&P Global Ratings, a division of S&P Global Inc. ("S&P") or Fitch Ratings Inc. ("Fitch"), or at least Baa3 by Moody's Investors Service, Inc. ("Moody's"); and (iii) have at least \$15 million in face value outstanding (if a bond has already been included in an Underlying Index, then it need only have at least 80% of the initial minimum face value qualification (\$12 million in face value outstanding) to remain within the Underlying Index at rebalance). Bonds selected for inclusion in an Underlying Index are market value weighted, and the bonds of individual issuers are collectively limited to a maximum weighting of 5% prior to the final year of maturity of the Underlying Index.

Prior to the final year of maturity of an Underlying Index (*i.e.*, the year of the maturity or effective maturity of all Municipal Bonds within the Underlying Index), each Underlying Index is rebalanced monthly, at which time: (i) New bonds that meet the eligibility and

maturity (or effective maturity)¹² criteria above are added to the Underlying Index; (ii) existing bonds that no longer meet the eligibility requirements are removed; and (iii) weights of Underlying Index components are reset to reflect current market value. The Index Provider only reevaluates the effective maturity date of bonds already included in the investment universe semi-annually, as part of the June and December rebalances, at which time in addition to bonds being added or removed from the Underlying Indexes pursuant to the eligibility screening described in the previous paragraph, bonds also may be added or removed from the Underlying Indexes due to any changes in effective maturity (*i.e.*, they no longer have an effective maturity in the year indicated by the Underlying Index's name).

If a bond is removed from an Underlying Index during any monthly rebalance, such bond will be excluded for the next three monthly rebalances (including the current rebalance).

During the final year of maturity (*i.e.*, the year of the maturity or effective maturity of all Municipal Bonds within the Underlying Index), the Underlying Indexes do not rebalance or add new Municipal Bonds. As Municipal Bonds included in the Underlying Indexes are called or mature, the Underlying Indexes will transition to VRDOs. To be included in the Underlying Index, such VRDOs must have an investment grade credit rating (based on an average of ratings from S&P, Fitch and Moody's) and have at least \$10 million in face value outstanding. Each Fund's portfolio is rebalanced in accordance with its applicable Underlying Index.

The Municipal Bonds in which a Fund invests have an actual or effective year of maturity in the year indicated by its name, and each Fund will terminate on or about December 15 of such year. For example, the Invesco BulletShares 2021 Municipal Bond ETF will terminate on or about December 15, 2021. The Board of Trustees of the Trust (the "Board") may change the termination date to an earlier or later date without shareholder approval. In the final year of operation, when the Municipal Bonds held by a Fund are called or mature, the proceeds will not be reinvested in the Municipal Bonds within the Underlying Index but instead, in connection with the Underlying Index's transition to VRDOs,

the Fund's portfolio will transition to any combination of VRDOs,¹³ certain derivatives,¹⁴ ETFs,¹⁵ including ETFs advised by the Adviser, cash and cash equivalents, including shares of money market funds advised by the Adviser or its affiliates and investment grade short-term commercial paper,¹⁶ as well as Municipal Bonds not included in its respective Underlying Index, but which the Adviser believes will help the Fund track the Underlying Index.

Each Fund has elected and intends to qualify each year as a "regulated investment company" (sometimes referred to as a "RIC") under Subchapter M of Chapter 1 of Subtitle A of the

¹³ VRDOs are tax-exempt obligations issued by U.S. states, state agencies, territories and possessions of the United States, the District of Columbia, or local government that contain a floating or variable interest rate adjustment formula and a right of demand on the part of the holder thereof to receive payment of the unpaid principal balance plus accrued interest upon a short notice period not to exceed seven days.

¹⁴ The Funds may invest in the following derivative instruments: Exchange-traded futures on fixed income securities, fixed income security indices, interest rates and currencies; exchange-traded and over-the-counter ("OTC") options on fixed income securities, interest rates, currencies, interest rate futures contracts, and fixed income security indices; exchange-traded and OTC interest rate and inflation swaps; and OTC total return swaps and forwards on fixed income securities, fixed income security indices, and fixed income security futures. See "Other Investments of the Funds" for additional information on the Funds' investments in derivatives. At least 90% of each Fund's net assets that are invested in listed derivatives will be invested in instruments that trade in markets that are members or affiliates of members of the Intermarket Surveillance Group ("ISG") or are parties to a comprehensive surveillance sharing agreement with the Exchange.

¹⁵ The ETFs in which a Fund may invest include Index Fund Shares (as described in Nasdaq Rule 5705(b)), Portfolio Depositary Receipts (as described in Nasdaq Rule 5705(a)), and Managed Fund Shares (as described in Nasdaq Rule 5735). The shares of ETFs in which a Fund may invest will be limited to securities that trade in markets that are members of the ISG, which includes all U.S. national securities exchanges, or exchanges that are parties to a comprehensive surveillance sharing agreement with the Exchange. A Fund will not invest in leveraged or inverse-leveraged ETFs. A Fund will not invest in non-U.S. exchanged-listed ETFs.

¹⁶ In addition to general commercial paper, the Funds may hold short-term tax-exempt notes (such as bond anticipation notes (BANs), tax anticipation notes (TANs), tax and revenue anticipation notes (TRANs) and revenue anticipation notes (RANs)). Such instruments are short-term notes issued by U.S. states, state agencies, territories and possessions of the United States, the District of Columbia, or local government and payable from a defined source of anticipated revenues (*e.g.*, BANs are repaid from the proceeds of issuance of long-term bonds whereas TRANs are repaid from future tax receipts and revenues of the government unit). Although the index methodology for each Underlying Index does not contemplate the inclusion of commercial paper or municipal notes in the Underlying Indexes, the Adviser may utilize such instruments in furtherance of a Funds' investment strategy.

¹⁰ As used herein, VRDOs are separate from, and not included in the definition of, Municipal Bonds.

¹¹ For example, bonds contained in the Invesco BulletShares® Municipal Bond 2021 Index will have actual or effective maturities in the year 2021.

¹² Effective maturity is established at each monthly rebalance only for new bonds that have been issued since the last rebalance. Effective maturity for all other bonds currently in the investment universe are not reevaluated, except during the June and December rebalances.

Internal Revenue Code of 1986, as amended.¹⁷

Other Investments of the Funds

While under normal market conditions a Fund will invest at least 80% of its assets pursuant to the Index Tracking Policy described above, each Fund may invest its remaining assets in VRDOs, certain derivatives, ETFs, including ETFs advised by the Adviser, cash and cash equivalents, including shares of money market funds advised by the Adviser or its affiliates and short-term investment grade commercial paper,¹⁸ as well as Municipal Bonds not included in its respective Underlying Index, but which the Adviser believes will help the Fund track the Underlying Index.

Investment Restrictions of the Funds

Each Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment), including commercial instruments deemed illiquid by the Adviser.¹⁹ Each Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of the Fund's net assets are held in illiquid securities or other illiquid assets. Illiquid securities and other illiquid assets shall be determined in accordance with Commission staff guidance.²⁰

¹⁷ 26 U.S.C. 851.

¹⁸ See *supra* footnotes 13–16 for descriptions of all such instruments.

¹⁹ In reaching liquidity decisions, the Adviser may consider the following factors: The frequency of trades and quotes for the security; the number of dealers wishing to purchase or sell the security and the number of other potential purchasers; dealer undertakings to make a market in the security; and the nature of the security and the nature of the marketplace in which it trades (*e.g.*, the time needed to dispose of the security, the method of soliciting offers and the mechanics of transfer).

²⁰ Long-standing Commission guidelines have required open-end funds to hold no more than 15% of their net assets in illiquid securities and other illiquid assets. See Investment Company Act Release No. 28193 (March 11, 2008), 73 FR 14618 (March 18, 2008), FN 34. See also Investment Company Act Release Nos. 5847 (October 21, 1969), 35 FR 19989 (December 31, 1970) (Statement Regarding “Restricted Securities”); and 18612 (March 12, 1992), 57 FR 9828 (March 20, 1992) (Revisions of Guidelines to Form N-1A). A fund's portfolio security is illiquid if it cannot be disposed of in the ordinary course of business within seven days at approximately the value ascribed to it by the fund. See Investment Company Act Release Nos. 14983 (March 12, 1986), 51 FR 9773 (March 21, 1986) (adopting amendments to Rule 2a-7

Each Fund's investments will be consistent with the Fund's investment objective. A Fund's investments will not be used to enhance leverage. That is, while a Fund will be permitted to borrow as permitted under the 1940 Act, no Fund will be operated as a “leveraged ETF,” *i.e.*, it will not be operated in a manner designed to seek a multiple or inverse multiple of the performance of the Fund's Underlying Index (as defined in its investment objective).

Descriptions of the Underlying Indexes

Each Fund will seek to track the investment results (before fees and expenses) of its Underlying Index. The Exchange is submitting this proposed rule change because the Underlying Index for each Fund does not meet all of the “generic” listing requirements of Rule 5705(b)(4)(A) applicable to the listing of Index Fund Shares based on fixed income securities indexes. Each Underlying Index (both prior to its final year of maturity, and as it transitions to VRDOs in its final year) meets all such requirements except for those set forth in Rule 5705(b)(4)(A)(ii).²¹ Although the Underlying Indexes do not meet the requirements of Rule 5705(b)(4)(A)(ii), they each have substitute characteristics that support their listing, as discussed below for each Underlying Index.

2021 Index

As of May 31, 2019, 94.34% of the weight of the 2021 Index components was comprised of individual bonds that were part of a larger Municipal Bond offering with a total minimum original principal amount outstanding of \$100 million or more for all bonds within the offering in aggregate. In addition, the aggregate face amount outstanding of bonds in the 2021 Index was approximately \$94.63 billion, the total market value of the bonds was approximately \$102.44 billion, and the average face amount outstanding per bond in the 2021 Index was approximately \$38.40 million. Further, the most heavily weighted component represented 0.85% of the weight of the 2021 Index and the aggregate weight of the five most heavily weighted components represented 2.85% of the weight of the 2021 Index.²²

under the 1940 Act); and 17452 (April 23, 1990), 55 FR 17933 (April 30, 1990) (adopting Rule 144A under the Securities Act of 1933).

²¹ *Supra* footnote 6.

²² Rule 5705(b)(4)(A)(iv) provides that no component fixed-income security (excluding Treasury Securities) will represent more than 30% of the Fixed Income Securities portion of the weight of the index or portfolio, and the five highest weighted component fixed-income securities do not in the aggregate account for more than 65% of the

Given these statistics, and the fact that the 2021 Index is comprised of over 500 bonds (as of May 31, 2019, the 2021 Index was composed of 2,464 bonds from issuers in 52 different states or U.S. territories), the Exchange believes that, notwithstanding that the 2021 Index does not satisfy the criterion in Rule 5705(b)(4)(A)(ii), the 2021 Index is sufficiently broad-based to deter potential manipulation. In addition, a substantial portion (94.34%) of the 2021 Index weight is comprised of bonds that were part of a larger municipal offering with a total minimum original principal amount outstanding of \$100 million or more in aggregate, and in view of the substantial aggregate face amount outstanding of the bonds and the average face amount outstanding per 2021 Index component, as referenced above.²³ Further, 58.96% of the 2021 Index weight consisted of bonds with a rating of AA/Aa2 or higher.

2022 Index

As of May 31, 2019, 93.74% of the weight of the 2022 Index components was comprised of individual bonds that were part of a larger Municipal Bond offering with a total minimum original principal amount outstanding of \$100 million or more for all bonds within the offering in aggregate. In addition, the aggregate face amount outstanding of bonds in the 2022 Index was approximately \$110.53 billion, the total market value of the bonds was approximately \$121.58 billion, and the average face amount outstanding per bond in the 2022 Index was approximately \$38.46 million. Further, the most heavily weighted component represented 0.45% of the weight of the 2022 Index and the aggregate weight of the five most heavily weighted components represented 2.03% of the weight of the 2022 Index.

Given these statistics, and the fact that the 2022 Index is comprised of over 500 bonds (as of May 31, 2019, the 2022 Index was composed of 2,874 bonds from issuers in 51 different states or U.S. territories), the Exchange believes that, notwithstanding that the 2022 Index does not satisfy the criterion in Rule 5705(b)(4)(A)(ii), the 2022 Index is sufficiently broad-based to deter potential manipulation. In addition, a substantial portion (93.74%) of the 2022 Index weight is comprised of bonds that were part of a larger municipal offering

Fixed Income Securities portion of the weight of the index or portfolio.

²³ The Adviser represents that when bonds are close substitutes for one another, pricing vendors can use executed trade information from all similar bonds as pricing inputs for an individual security. This can make individual securities more liquid.

with a total minimum original principal amount outstanding of \$100 million or more in aggregate, and in view of the substantial aggregate face amount outstanding of the bonds and the average face amount outstanding per 2022 Index component, as referenced above. Further, 49.71% of the 2022 Index weight consisted of bonds with a rating of AA/Aa2 or higher.

2023 Index

As of May 31, 2019, 92.87% of the weight of the 2023 Index components was comprised of individual bonds that were part of a larger Municipal Bond offering with a total minimum original principal amount outstanding of \$100 million or more for all bonds within the offering in aggregate. In addition, the aggregate face amount outstanding of bonds in the 2023 Index was approximately \$98.34 billion, the total market value of the bonds was approximately \$111.13 billion, and the average face amount outstanding per bond in the 2023 Index was approximately \$40.24 million. Further, the most heavily weighted component represented 0.61% of the weight of the 2023 Index and the aggregate weight of the five most heavily weighted components represented 2.80% of the weight of the 2023 Index.

Given these statistics, and the fact that the 2023 Index is comprised of over 500 bonds (as of May 31, 2019, the 2023 Index was composed of 2,444 bonds from issuers in 49 different states or U.S. territories), the Exchange believes that, notwithstanding that the 2023 Index does not satisfy the criterion in Rule 5705(b)(4)(A)(ii), the 2023 Index is sufficiently broad-based to deter potential manipulation. In addition, a substantial portion (92.87%) of the 2023 Index weight is comprised of bonds that were part of a larger municipal offering with a total minimum original principal amount outstanding of \$100 million or more in aggregate, and in view of the substantial aggregate face amount outstanding of the bonds and the average face amount outstanding per 2023 Index component, as referenced above. Further, 48.68% of the 2023 Index weight consisted of bonds with a rating of AA/Aa2 or higher.

2024 Index

As of May 31, 2019, 94.81% of the weight of the 2024 Index components was comprised of individual bonds that were part of a larger Municipal Bond offering with a total minimum original principal amount outstanding of \$100 million or more for all bonds within the offering in aggregate. In addition, the aggregate face amount outstanding of

bonds in the 2024 Index was approximately \$95.12 billion, the total market value of the bonds was approximately \$109.47 billion, and the average face amount outstanding per bond in the 2024 Index was approximately \$38.78 million. Further, the most heavily weighted component represented 0.53% of the weight of the 2024 Index and the aggregate weight of the five most heavily weighted components represented 2.38% of the weight of the 2024 Index.

Given these statistics, and the fact that the 2024 Index is comprised of over 500 bonds (as of May 31, 2019, the 2024 Index was composed of 2,453 bonds from issuers in 48 different states or U.S. territories), the Exchange believes that, notwithstanding that the 2024 Index does not satisfy the criterion in Rule 5705(b)(4)(A)(ii), the 2024 Index is sufficiently broad-based to deter potential manipulation. In addition, a substantial portion (94.81%) of the 2024 Index weight is comprised of bonds that were part of a larger municipal offering with a total minimum original principal amount outstanding of \$100 million or more in aggregate, and in view of the substantial aggregate face amount outstanding of the bonds and the average face amount outstanding per 2024 Index component, as referenced above. Further, 54.14% of the 2024 Index weight consisted of bonds with a rating of AA/Aa2 or higher.

2025 Index

As of May 31, 2019, 93.72% of the weight of the 2025 Index components was comprised of individual bonds that were part of a larger Municipal Bond offering with a total minimum original principal amount outstanding of \$100 million or more for all bonds within the offering in aggregate. In addition, the aggregate face amount outstanding of bonds in the 2025 Index was approximately \$101.69 billion, the market value of the bonds was approximately \$118.29 billion, and the average face amount outstanding per bond in the 2025 Index was approximately \$37.73 million. Further, the most heavily weighted component represented 0.57% of the weight of the 2025 Index and the aggregate weight of the five most heavily weighted components represented 2.11% of the weight of the 2025 Index.

Given these statistics, and the fact that the 2025 Index is comprised of over 500 bonds (as of May 31, 2019, the 2025 Index was composed of 2,695 bonds from issuers in 48 different states or U.S. territories), the Exchange believes that, notwithstanding that the 2025 Index does not satisfy the criterion in

Rule 5705(b)(4)(A)(ii), the 2025 Index is sufficiently broad-based to deter potential manipulation. In addition, a substantial portion (93.72%) of the 2025 Index weight is comprised of bonds that were part of a larger municipal offering with a total minimum original principal amount outstanding of \$100 million or more in aggregate, and in view of the substantial aggregate face amount outstanding of the bonds and the average face amount outstanding per 2025 Index component, as referenced above. Further, 52.78% of the 2025 Index weight consisted of bonds with a rating of AA/Aa2 or higher.

2026 Index

As of May 31, 2019, 95.07% of the weight of the 2026 Index components was comprised of individual bonds that were part of a larger Municipal Bond offering with a total minimum original principal amount outstanding of \$100 million or more for all bonds within the offering in aggregate. In addition, the aggregate face amount outstanding of bonds in the 2026 Index was approximately \$112.32 billion, the total market value of the bonds was approximately \$131.57 billion, and the average face amount outstanding per bond in the 2026 Index was approximately \$36.74 million. Further, the most heavily weighted component represented 0.43% of the weight of the 2026 Index and the aggregate weight of the five most heavily weighted components represented 1.66% of the weight of the 2026 Index.

Given these statistics, and the fact that the 2026 Index is comprised of over 500 bonds (as of May 31, 2019, the 2026 Index was composed of 3,057 bonds from issuers in 47 different states or U.S. territories), the Exchange believes that, notwithstanding that the 2026 Index does not satisfy the criterion in Rule 5705(b)(4)(A)(ii), the 2026 Index is sufficiently broad-based to deter potential manipulation. In addition, a substantial portion (95.07%) of the 2026 Index weight is comprised of bonds that were part of a larger municipal offering with a total minimum original principal amount outstanding of \$100 million or more in aggregate, and in view of the substantial aggregate face amount outstanding of the bonds and the average face amount outstanding per 2026 Index component, as referenced above. Further, 50.35% of the 2026 Index weight consisted of bonds with a rating of AA/Aa2 or higher.

2027 Index

As of May 31, 2019, 94.90% of the weight of the 2027 Index components was comprised of individual bonds that

were part of a larger Municipal Bond offering with a total minimum original principal amount outstanding of \$100 million or more for all bonds within the offering in aggregate. In addition, the aggregate face amount outstanding of bonds in the 2027 Index was approximately \$100.30 billion, the total market value of the bonds was approximately \$118.71 billion, and the average face amount outstanding per bond in the 2027 Index was approximately \$38.30 million. Further, the most heavily weighted component represented 0.71% of the weight of the 2027 Index and the aggregate weight of the five most heavily weighted components represented 2.58% of the weight of the 2027 Index.

Given these statistics, and the fact that the 2027 Index is comprised of over 500 bonds (as of May 31, 2019, the 2027 Index was composed of 2,619 bonds from issuers in 51 different states or U.S. territories), the Exchange believes that, notwithstanding that the 2027 Index does not satisfy the criterion in Rule 5705(b)(4)(A)(ii), the 2027 Index is sufficiently broad-based to deter potential manipulation. In addition, a substantial portion (94.90%) of the 2027 Index weight is comprised of bonds that were part of a larger municipal offering with a total minimum original principal amount outstanding of \$100 million or more in aggregate, and in view of the substantial aggregate face amount outstanding of the bonds and the average face amount outstanding per 2027 Index component, as referenced above. Further, 52.90% of the 2027 Index weight consisted of bonds with a rating of AA/Aa2 or higher.

2028 Index

As of May 31, 2019, 94.63% of the weight of the 2028 Index components was comprised of individual bonds that were part of a larger Municipal Bond offering with a total minimum original principal amount outstanding of \$100 million or more for all bonds within the offering in aggregate. In addition, the aggregate face amount outstanding of bonds in the 2028 Index was approximately \$74.66 billion, the total market value of the bonds was approximately \$89.17 billion, and the average face amount outstanding per bond in the 2028 Index was approximately \$42.13 million. Further, the most heavily weighted component represented 0.68% of the weight of the 2028 Index and the aggregate weight of the five most heavily weighted components represented 2.71% of the weight of the 2028 Index.

Given these statistics, and the fact that the 2028 Index is comprised of over 500

bonds (as of May 31, 2019, the 2028 Index was composed of 1,772 bonds from issuers in 48 different states or U.S. territories), the Exchange believes that, notwithstanding that the 2028 Index does not satisfy the criterion in Rule 5705(b)(4)(A)(ii), the 2028 Index is sufficiently broad-based to deter potential manipulation. In addition, a substantial portion (94.63%) of the 2028 Index weight is comprised of bonds that were part of a larger municipal offering with a total minimum original principal amount outstanding of \$100 million or more in aggregate, and in view of the substantial aggregate face amount outstanding of the bonds and the average face amount outstanding per 2028 Index component, as referenced above. Further, 54.39% of the 2028 Index weight consisted of bonds with a rating of AA/Aa2 or higher.

2029 Index

As of May 31, 2019, 96.28% of the weight of the 2029 Index components was comprised of individual bonds that were part of a larger Municipal Bond offering with a total minimum original principal amount outstanding of \$100 million or more for all bonds within the offering in aggregate. In addition, the aggregate face amount outstanding of bonds in the 2029 Index was approximately \$24.27 billion, the total market value of the bonds was approximately \$29.19 billion, and the average face amount outstanding per bond in the 2029 Index was approximately \$39.15 million. Further, the most heavily weighted component represented 1.18% of the weight of the 2029 Index and the aggregate weight of the five most heavily weighted components represented 5.13% of the weight of the 2029 Index.

Given these statistics, and the fact that the 2029 Index is comprised of over 500 bonds (as of May 31, 2019, the 2029 Index was composed of 620 bonds from issuers in 39 different states or U.S. territories), the Exchange believes that, notwithstanding that the 2029 Index does not satisfy the criterion in Rule 5705(b)(4)(A)(ii), the 2029 Index is sufficiently broad-based to deter potential manipulation. In addition, a substantial portion (96.28%) of the 2029 Index weight is comprised of bonds that were part of a larger municipal offering with a total minimum original principal amount outstanding of \$100 million or more in aggregate, and in view of the substantial aggregate face amount outstanding of the bonds and the average face amount outstanding per 2029 Index component, as referenced above. Further, 50.47% of the 2029

Index weight consisted of bonds with a rating of AA/Aa2 or higher.

All Underlying Indexes

Each Underlying Index will, on a continuous basis, contain at least 500 component securities. In addition, prior to its final year, at least 90% of the weight of each Underlying Index will be comprised of Municipal Bonds that have an outstanding face amount per bond of at least \$10 million and were issued as part of a larger Municipal Bond offering with a total minimum original principal amount outstanding of \$100 million or more for all bonds within the offering in aggregate. During its final year, each Underlying Index will transition to VRDOs and, in doing so, at least 90% of the weight of the VRDO components of each Underlying Index will have an outstanding face amount per VRDO of at least \$10 million and at least 40% of the weight of the VRDO components of each Underlying Index will have been issued as part of a larger VRDO offering with a total minimum original principal amount outstanding of \$100 million or more for all VRDOs within the offering in aggregate.²⁴

Further, as each Underlying Index transitions to VRDOs in its final year, the Municipal Bond components that have not been called or matured (and therefore remain in the Underlying Index) will continue to meet the criteria discussed above (*i.e.*, 90% of the weight of the Municipal Bond components will have an outstanding face amount of at least \$10 million and will have been issued as part of a larger Municipal Bond offering with a total minimum original principal amount outstanding of \$100 million or more for all bonds within the offering in aggregate).

Each Underlying Index value, calculated and disseminated at least once daily, will be available from major market data vendors. The top ten constituents of each Underlying Index, including their coupon rates, maturity dates and weightings, as of the last day of the prior month are disclosed on the Index Provider's website at www.invescoindexing.com. The rules governing the Underlying Indexes are also available on the Index Provider's

²⁴ The Commission previously has approved a proposed rule change relating to listing and trading of an ETF based on a VRDO index. See Securities Exchange Act Release No. 82295 (December 12, 2017), 82 FR 60056 (December 18, 2017) (SR-NYSEArca-2017-56) (notice of filing of Amendment No. 3 and order granting accelerated approval of a proposed rule change, as modified by Amendment No. 3, to list and trade shares of twelve series of investment company units pursuant to NYSE Arca Rule 5.2-E(j)(3)) (the "Comparable VRDO Filing").

website and described in each Fund's prospectus. In addition, as more fully described below, the portfolio of securities held by each Fund will be disclosed daily on the Funds' website at www.invesco.com/ETFs.

Discussion

Based on the characteristics of the Underlying Indexes and the representations made in the Descriptions of the Underlying Indexes and All Underlying Indexes sections above, the Exchange believes it is appropriate to allow the listing and trading of the Shares. The Underlying Indexes and Funds (both prior to its final year of maturity, and as it transitions to VRDOs in its final year) each satisfy all of the generic listing requirements of Rule 5705(b)(4)(A) applicable to the listing of Index Fund Shares based on fixed income securities indexes, except for the minimum principal amount outstanding requirement of Rule 5705(b)(4)(A)(ii). The Exchange notes that the representations in the Descriptions of the Underlying Indexes and All Underlying Indexes sections include substantially similar representations: (i) Regarding the Municipal Bond components of the Underlying Indexes, to the representations that appear in the Comparable Filing with respect to the S&P AMT-Free Municipal Callable Factor Adjusted 2026 Series Index, the S&P AMT-Free Municipal Callable Factor Adjusted 2027 Series Index, and the S&P AMT-Free Municipal Callable Factor Adjusted 2028 Series Index (collectively, with the S&P AMT-Free Municipal Callable Factor Adjusted 2026 Series Index and the S&P AMT-Free Municipal Callable Factor Adjusted 2027 Series Index, the "Comparable Indexes"); and (ii) regarding the VRDO components of the Underlying Indexes, to the representations that appear in the Comparable VRDO Filing with respect to the Bloomberg US Municipal AMT-Free Weekly VRDO Index (the "Comparable VRDO Index").²⁵

The Comparable Filing included the representation that a bond must be investment-grade and must have an outstanding par value of at least \$2 million in order to be included in the Comparable Indexes. Further, the Comparable Filing included a

representation that each Comparable Index will have at least 500 constituents on a continuous basis. Similarly, the Comparable VRDO Filing included the representation that at least 90% of the weight of the Comparable VRDO Index would be comprised of securities that have a minimum amount outstanding of \$10 million and, further, that the Comparable VRDO Index will have at least 500 constituents on a continuous basis. As noted above, each Underlying Index requires that, in order to remain in the Underlying Index, Municipal Bonds must be investment-grade and maintain a face value outstanding of over \$12 million and, as each Underlying Index transitions to VRDOs in its final year, such VRDO components must be investment-grade and maintain a face value outstanding of over \$10 million.

In addition, as stated above: (i) Prior to its final year, at least 90% of the weight of each Underlying Index will be comprised of Municipal Bonds that have an outstanding face amount per bond of at least \$10 million and were issued as part of a larger Municipal Bond offering with a total minimum original principal amount outstanding of \$100 million or more for all bonds within the offering in aggregate; and (ii) during its final year, as each Underlying Index transitions to VRDOs, at least 90% of the weight of the VRDO components of each Underlying Index will have an outstanding face amount per VRDO of at least \$10 million and at least 40% of the weight of the VRDO components of each Underlying Index will have been issued as part of a larger VRDO offering with a total minimum original principal amount outstanding of \$100 million or more for all VRDOs within the offering in aggregate. Further, the Adviser has represented that each Underlying Index will have at least 500 constituents on a continuous basis.

As such, the Exchange believes that the proposal is consistent with the Exchange Act because the representations regarding the quality and size of the issuances included in each Underlying Index provide a strong degree of protection against index manipulation that is consistent with other proposals that have either been approved for listing and trading by the Commission or were effective upon filing.

Availability of Information

The Funds' website www.invesco.com/ETFs, which is publicly available at no charge, will include the prospectus for each Fund that may be downloaded. On each Business Day, before commencement of

trading in Shares in the Regular Market Session²⁶ on the Exchange, the Adviser will disclose on the Funds' website the identities and quantities of the portfolio of securities and other assets in the daily disclosed portfolio held by the Funds that will form the basis for each Fund's calculation of net asset value ("NAV") at the end of the Business Day (the "Disclosed Portfolio"). The Disclosed Portfolio will include, as applicable: Ticker symbol, CUSIP number or other identifier, if any; a description of the holding (including the type of holding, such as the type of swap); the identity of the security, security index or other asset or instrument underlying the holding, if any; for options, the option strike price; quantity held (as measured by, for example, par value, notional value or number of shares, contracts or units); maturity date, if any; coupon rate, if any; effective date, if any; market value of the holding; and the percentage weighting of the holding in the Fund's portfolio. The website information will be publicly available at no charge.

The Funds' website will also include the ticker symbol for the Shares, CUSIP and exchange information, along with additional quantitative information updated on a daily basis, including, for each Fund: (1) Daily trading volume, the prior Business Day's reported NAV, closing price and mid-point of the bid/ask spread at the time of calculation of such NAV (the "Bid/Ask Price"),²⁷ and a calculation of the premium and discount of the Bid/Ask Price against the NAV; and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid/Ask Price against the NAV, within appropriate ranges, for the most recently completed calendar year and each of the four most recently completed calendar quarters since that year (or the life of the Fund if shorter).

Information regarding the Intra-day Indicative Value ("IIV") of the Shares is disseminated at least every 15 seconds throughout each trading day by the Reporting Authority (as that term is defined in Rule 5705(b)(1)(C)), including through the Nasdaq Information LLC proprietary index data service. However, the IIV should not be

²⁶ See Nasdaq Rule 4120(b)(4) (describing the three trading sessions on the Exchange: (1) Pre-Market Session from 4 a.m. to 9:30 a.m. E.T.; (2) Regular Market Session from 9:30 a.m. to 4 p.m. or 4:15 p.m. E.T.; and (3) Post-Market Session from 4 p.m. or 4:15 p.m. to 8 p.m. E.T.).

²⁷ The Bid/Ask Price of each Fund will be determined using the mid-point of the highest bid and the lowest offer on the Exchange as of the time of calculation of the Fund's NAV. The records relating to Bid/Ask Prices will be retained by each Fund and its service providers.

²⁵ Although the Comparable Indexes and Comparable VRDO Index differ in certain respects from the Municipal Bond components and VRDO components of the Underlying Indexes, respectively, including differences in certain criteria for inclusion, the Exchange believes that the Underlying Indexes and Funds provide substantially similar protections against index manipulation to those protections discussed in the Comparable Filing and Comparable VRDO Filing.

viewed as a “real-time” update of a Fund’s NAV. The dissemination of the IIV, together with the Disclosed Portfolio, will allow investors to determine the value of the underlying portfolio of a Fund on a daily basis and will provide a close estimate of that value throughout the trading day.

Intraday executable price quotations on Municipal Bonds and VRDOs held by a Fund and other assets held by a Fund not traded on an exchange, including OTC derivatives (OTC options, swaps and forwards) and cash equivalents will be available from major broker-dealer firms or market data vendors, as well as from automated quotation systems, published or other public sources, or online information services. Intra-day and closing price information related to cash and cash equivalents, including money market funds, investment grade short-term commercial paper and investment grade short-term tax-exempt notes, held by each Fund also will be available through subscription services, such as Bloomberg, Markit and Thomson Reuters, which can be accessed by Authorized Participants and other investors. The Municipal Securities Rulemaking Board’s (“MSRB”) Electronic Municipal Market Access (“EMMA”) will be a source of price information for Municipal Bonds. For exchange-traded assets, including ETFs, futures, certain options and swaps, such intraday information is available directly from the applicable listing exchange. In addition, price information for U.S. exchange-traded options will be available from the Options Price Reporting Authority.

Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers’ computer screens and other electronic services, and quotation and last-sale information for the Shares will be available via Nasdaq proprietary quote and trade services, as well as in accordance with the Unlisted Trading Privileges (“UTP”) plan and the Consolidated Tape Association (“CTA”) plans for the Shares. Information regarding the previous day’s closing price and trading volume for the Shares will be published daily in the financial section of newspapers.

Additional information regarding the Funds and the Shares, including investment strategies, risks, creation and redemption procedures, fees, portfolio holdings disclosure policies, distributions and taxes, will be included in the Registration Statement. Investors also will be able to obtain the Funds’ Statement of Additional Information

(“SAI”) and its Trust’s Form N-CEN, each of which is filed at least annually. Further, investors will be able to obtain each Fund’s Shareholder Reports and its Trust’s Form N-CSR, each of which is filed twice a year. The Funds’ SAI and Shareholder Reports will be available free upon request from the Trust, and those documents and the Form N-CSR and Form N-CEN may be viewed on-screen or downloaded from the Commission’s website at www.sec.gov.

Initial and Continued Listing of the Fund’s Shares

The Shares will conform to the initial and continued listing criteria applicable to Index Fund Shares, as set forth under Rule 5705, except Rule 5705(b)(4)(A)(ii). The Exchange represents that, for initial and continued listing, each Fund will be in compliance with Rule 10A-3²⁸ under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). A minimum of 100,000 Shares will be outstanding for each Fund at the commencement of trading on the Exchange. The Exchange will obtain a representation from the issuer of the Shares that the NAV per Share for each Fund will be calculated daily and that the NAV and the Disclosed Portfolio of each Fund will be made available to all market participants at the same time.

Trading Halts of the Funds’ Shares

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of a Fund. Nasdaq will halt trading in the Shares under the conditions specified in Nasdaq Rules 4120 and 4121, including the trading pauses under Nasdaq Rules 4120(a)(12). Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the securities and/or the financial instruments constituting the Disclosed Portfolio of a Fund; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares also will be subject to Nasdaq Rule 5705(b)(9), which sets forth circumstances under which Index Fund Shares may be halted.

Trading Rules

Nasdaq deems the Shares to be equity securities, thus rendering trading in the Shares subject to Nasdaq’s existing rules governing the trading of equity securities. Regular market session

trading, in accordance with Nasdaq Rule 5705(b)(7), will occur between 9:30 a.m. and either 4:00 p.m. or 4:15 p.m. for each series of Index Fund Shares, as specified by Nasdaq. In addition, Nasdaq may designate each series of Index Fund Shares for trading during a pre-market session beginning at 4:00 a.m. and/or a post-market session ending at 8:00 p.m. The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.

Surveillance

The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by the Exchange and also by FINRA, on behalf of the Exchange.²⁹ Such trading surveillances are designed to detect violations of Exchange rules and applicable federal securities laws. The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws.

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations. FINRA, on behalf of the Exchange, will communicate as needed regarding trading in the Shares and exchange-traded securities and instruments held by the Funds with other markets and other entities that are members of the ISG,³⁰ and FINRA may obtain trading information regarding trading in the Shares and exchange-traded securities and instruments held by a Fund (including ETFs and exchange-traded derivatives) from such markets and other entities. Moreover, FINRA, on behalf of the Exchange, will be able to access, as needed, trade information for certain debt securities held by each Fund reported to FINRA’s TRACE, or the MSRB.

In addition, the Exchange will communicate as needed and may obtain information regarding trading in the Shares and exchange-traded securities and instruments held by a Fund from markets and other entities that are

²⁹ FINRA surveils trading on the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA’s performance under this regulatory services agreement.

³⁰ For a list of the current members of ISG, see www.isgportal.org.

²⁸ See 17 CFR 240.10A-3.

members of ISG, which includes securities exchanges, or with which the Exchange has in place a comprehensive surveillance sharing agreement.³¹

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

In addition, the Exchange represents that the Shares will comply with all other requirements applicable to Index Fund Shares, which includes requirements relating to the dissemination of key information such as the Underlying Index value, the NAV, and the IIV, rules governing the trading of equity securities, trading hours, trading halts, fire walls for the Index Provider and Adviser, surveillance, and the Information Bulletin, as set forth in Exchange rules applicable to Index Fund Shares and the orders approving such rules.

Information Circular

Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (1) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (2) Nasdaq Rule 2111A, which imposes suitability obligations on Nasdaq members with respect to recommending transactions in the Shares to customers; (3) how information regarding the IIV and the Disclosed Portfolio is disseminated; (4) the risks involved in trading the Shares during the Pre-Market and Post-Market Sessions when an updated IIV will not be calculated or publicly disseminated; (5) the requirement that members purchasing Shares from the Funds for resale to investors deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (6) trading information.

In addition, the Information Circular will advise members, prior to the commencement of trading, of the prospectus delivery requirements applicable to each Fund. Members purchasing Shares from the Funds for resale to investors will deliver a prospectus to such investors. The Information Circular will also discuss any exemptive, no-action and interpretive relief granted by the

Commission from any rules under the Exchange Act.

Additionally, the Information Circular will reference that each Fund is subject to various fees and expenses. The Information Circular will also disclose the trading hours of the Shares and the applicable NAV calculation time for the Funds. The Information Circular will disclose that information about the Shares will be publicly available on the Funds' website.

Continued Listing Representations

All statements and representations made in this filing regarding (a) index composition; (b) the description of the portfolios; (c) limitations on portfolio holdings or reference assets, (d) dissemination and availability of the indexes or intraday indicative values, or (e) the applicability of Exchange listing rules specified in this rule filing shall constitute continued listing requirements for listing the Shares on the Exchange. In addition, the issuer has represented to the Exchange that it will advise the Exchange of any failure by a Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. If a Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under the Nasdaq 5800 Series.

2. Statutory Basis

Nasdaq believes that the proposal is consistent with Section 6(b) of the Exchange Act, in general, and Section 6(b)(5)³² of the Exchange Act, in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in Nasdaq Rule 5705 (with the exception of Rule 5705(b)(4)(A)(ii)). The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by the

Exchange and also by FINRA, on behalf of the Exchange. Such trading surveillances are designed to deter and detect violations of Exchange rules and applicable federal securities laws and are adequate to properly monitor trading in the Shares in all trading sessions.

The Adviser is not a broker-dealer, but is affiliated with a broker-dealer and has implemented and will maintain a "fire wall" with respect to its broker-dealer affiliate regarding access to information concerning the composition and/or changes to each Fund's portfolio. In the event (a) the Adviser becomes newly affiliated with a different broker-dealer (or becomes a registered broker-dealer itself), or (b) any new adviser or sub-adviser to a Fund is a registered broker-dealer or becomes affiliated with a broker-dealer, each will implement and maintain a fire wall with respect to its relevant personnel and/or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition and/or changes to each Fund's portfolio and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding each Fund's portfolio.

In addition, Nasdaq Rule 5705(b)(4)(B)(i) requires that if an Index Fund Share's underlying index maintained by a broker-dealer or fund advisor, the broker-dealer or fund advisor shall erect and maintain a "fire wall" around the personnel who have access to information concerning changes and adjustments to the index and the index shall be calculated by a third party who is not a broker-dealer or fund advisor. In addition, Nasdaq Rule 5705 further requires that any advisory committee, supervisory board, or similar entity that makes decisions on the index composition, methodology and related matters, must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material non-public information regarding the applicable index. As noted above, the Index Provider has implemented and will continue to maintain the fire wall required.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of additional types of passively-managed exchange-traded products that will enhance competition among market participants, to the benefit of investors and the marketplace.

As addressed above, the Exchange believes that, notwithstanding that the Underlying Indexes do not satisfy the criterion in Rule 5705(b)(4)(A)(ii), the

³¹ The Exchange notes that not all components of the Disclosed Portfolio for each Fund may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

³² 15 U.S.C. 78(f)(b)(5).

Underlying Indexes are, and would remain, sufficiently broad-based to deter potential manipulation; each Underlying Index will, on a continuous basis, contain at least 500 component securities. Whereas Rule 5705(b)(4)(A)(v) requires that an index contain securities from a minimum of 13 non-affiliated issuers, as of May 31, 2019, the Underlying Indexes each include securities issued by municipal entities in at least 39 states or U.S. territories. Further, whereas the generic listing rules permit a single component fixed-income security to represent up to 30% of the fixed income securities portion of the weight of an index and the top five components to, in aggregate, represent up to 65% of the fixed income securities portion of the weight of an index, the largest component security in each Underlying Index constitutes no more than 1.18% of the weight of an Underlying Index and the largest five component securities represent no more than 5.13% of the weight of an Underlying Index.

The Exchange believes that this significant diversification and the lack of concentration among constituent securities provide each Underlying Index with a strong degree of protection against index manipulation. Each Underlying Index and Fund satisfy all of the generic listing requirements for Index Fund Shares based on a fixed income index, except for the minimum principal amount outstanding requirement of Rule 5705(b)(4)(A)(ii). With this in mind, the Exchange notes that the representations in the Descriptions of the Underlying Indexes and All Underlying Indexes sections are substantially similar to the representations made regarding the Comparable Indexes and the Comparable VRDO Index in the Comparable Filing and Comparable VRDO Filing, respectively.

The Comparable Filing included the representation that a bond must be investment-grade and must have an outstanding par value of at least \$2 million in order to be included in the Comparable Indexes. Further, the Comparable Filing included a representation that each Comparable Index will have at least 500 constituents on a continuous basis. Similarly, the Comparable VRDO Filing included the representation that at least 90% of the weight of the Comparable VRDO Index would be comprised of securities that have a minimum amount outstanding of \$10 million and, further, that the Comparable VRDO Index will have at least 500 constituents on a continuous basis. As noted above, each Underlying Index requires that, in order to remain

in the Underlying Index, Municipal Bonds must be investment-grade and maintain a face value outstanding of over \$12 million and, as the Underlying Indexes transition to VRDOs in their final year, VRDO components of the Underlying Indexes must also be investment grade and have a face value outstanding of over \$10 million.

In addition, as stated above: (i) Prior to its final year, at least 90% of the weight of each Underlying Index will be comprised of Municipal Bonds that have an outstanding face amount per bond of at least \$10 million and were issued as part of a larger Municipal Bond offering with a total minimum original principal amount outstanding of \$100 million or more for all bonds within the offering in aggregate; and (ii) during its final year, as each Underlying Index transitions to VRDOs, at least 90% of the weight of the VRDO components of each Underlying Index will have an outstanding face amount per VRDO of at least \$10 million and at least 40% of the weight of the VRDO components of each Underlying Index will have been issued as part of a larger VRDO offering with a total minimum original principal amount outstanding of \$100 million or more for all VRDOs within the offering in aggregate. Further, the Adviser has represented that each Underlying Index will have at least 500 constituents on a continuous basis.

As such, the Exchange believes that the proposal is consistent with the Exchange Act because the representations regarding the quality and size of the issuances included in each Underlying Index provide a strong degree of protection against index manipulation that is consistent with other proposals that have either been approved for listing and trading by the Commission or were effective upon filing.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily every day that the Funds are traded, and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time. In addition, a large amount of information will be publicly available regarding the Funds and the Shares, thereby promoting market transparency. Moreover, the IIV, available on the Nasdaq Information LLC proprietary index data service, will be widely disseminated by one or more major market data vendors at least every 15 seconds during the Exchange's Regular Market Session. On each

Business Day, before commencement of trading in Shares in the Regular Market Session on the Exchange, the Adviser will disclose on the Funds' website the Disclosed Portfolios of the Funds that will form the basis for each Fund's calculation of NAV at the end of the Business Day.

Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services, and quotation and last-sale information for the Shares will be available via Nasdaq proprietary quote and trade services, as well as in accordance with the UTP plan and the CTA plans for the Shares.

The Funds' website will include a form of the prospectus for each Fund and additional data relating to NAV and other applicable quantitative information. Moreover, prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Trading in Shares of the Funds will be halted under the conditions specified in Nasdaq Rules 4120 and 4121 or because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. In addition, as noted above, investors will have ready access to information regarding each Fund's holdings, the IIV, the Disclosed Portfolio, and quotation and last sale information for the Shares.

For the above reasons, Nasdaq believes the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Exchange Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act. The Exchange believes that the proposed rule change will facilitate the listing and trading of additional types of passively-managed exchange-traded products that will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act³³ and Rule 19b-4(f)(6) thereunder.³⁴

A proposed rule change filed under Rule 19b-4(f)(6)³⁵ normally does not become operative for 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),³⁶ the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay to allow the Funds to begin listing and trading on the Exchange without delay. The Exchange states that its representations regarding the requirements for each Underlying Index are substantially similar to those included in relation to the Comparable Indexes and Comparable VRDO Index in the Comparable Filing and Comparable VRDO Filing, respectively. Moreover, according to the Exchange, waiver of the 30-day operative delay will more quickly facilitate the listing and trading of additional exchange-traded products that will enhance competition among market participants, to the benefit of investors and the marketplace. For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission waives the 30-day operative delay and designates the proposed rule change operative upon filing.³⁷

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if

it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NASDAQ-2019-070 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.
- All submissions should refer to File Number SR-NASDAQ-2019-070. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish

to make available publicly. All submissions should refer to File Number SR-NASDAQ-2019-070, and should be submitted on or before October 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁸

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019-19903 Filed 9-13-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-86920; File No. SR-CBOE-2019-056]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Cboe Trade Match System

September 10, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on September 5, 2019, Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³ and Rule 19b-4(f)(6) thereunder.⁴ 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

Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") proposes to update the Exchange's Rules regarding the Cboe Trade Match System ("CTM") and move those Rules from the currently effective Rulebook ("current Rulebook") to the shell structure for the Exchange's Rulebook that will become effective upon the migration of the Exchange's trading platform to the same system used by the Cboe Affiliated Exchanges (as defined below) ("shell Rulebook"). The text of the proposed rule change is provided in Exhibit 5.

³⁸ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴ 17 CFR 240.19b-4(f)(6).

³³ 15 U.S.C. 78s(b)(3)(A).

³⁴ 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.

³⁵ 17 CFR 240.19b-4(f)(6).

³⁶ 17 CFR 240.19b-4(f)(6)(iii).

³⁷ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

The text of the proposed rule change is also available on the Exchange's website (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In 2016, the Exchange's parent company, Cboe Global Markets, Inc. (formerly named CBOE Holdings, Inc.) ("Cboe Global"), which is also the parent company of Cboe C2 Exchange, Inc. ("C2"), acquired Cboe EDGA Exchange, Inc. ("EDGA"), Cboe EDGX Exchange, Inc. ("EDGX" or "EDGX Options"), Cboe BZX Exchange, Inc. ("BZX" or "BZX Options"), and Cboe BYX Exchange, Inc. ("BYX" and, together with Cboe Options, C2, EDGX, EDGA, and BZX, the "Cboe Affiliated Exchanges"). Cboe Options intends to migrate its trading platform to the same system used by the Cboe Affiliated Exchanges, which the Exchange expects to complete on October 7, 2019. In connection with this technology migration, the Exchange has a shell Rulebook that resides alongside its current Rulebook, which shell Rulebook will contain the Rules that will be in place upon completion of the Cboe Options technology migration.

The Exchange proposes to harmonize current Rule 6.67 in connection with the Cboe Trade Match System ("CTM"), which allows authorized Trading Permit Holders ("TPHs") to add and/or update trade records, to C2 Rule 6.31, which provides for the "Clearing Editor" and is functionally equivalent to CTM. The Exchange now proposes Rule 6.6 in the shell Rulebook, which will govern the Exchange's Clearing Editor upon migration, and to delete Rule 6.67 from

the current Rulebook, also upon migration. The Exchange proposes to amend the rule to conform to the Clearing Editor functionality and rule language of that of C2 to the extent necessary to retain intended differences unique to Cboe Options market-model, functionality, and/or rule text, which are identified below. The Exchange also proposes to make non-substantive changes by updating cross-references to rules in the shell Rulebook and rules not yet in the shell Rulebook but that in the Exchange intends to move to the shell Rulebook and, as a result of consolidating and conforming the proposed rule to the corresponding C2 rule, make non-substantive changes that simplify and update the rule text to read in plain English and reformat the paragraph lettering and/or numbering.

Specifically, the Clearing Editor under proposed Rule 6.6, like CTM, allows TPHs to update executed trades on their trading date and revise them for clearing. Proposed Rule 6.6(a) is substantively the same as the current general language under Rule 6.67 and is consistent with corresponding C2 Rule 6.31(a). The Exchange maintains that along with using Clearing Editor to correct certain bona fide errors, TPHs may use it to update information entered pursuant to Rule 6.1 in the shell Rulebook (current Rule 6.51).⁵ The proposed rule maintains this difference between it and C2 Rule 6.31 as it relates to the systemization or report of an order executed in open outcry which is unique to Cboe Options. Proposed Rule 6.6(b) is also substantially similar to current 6.67(a). The proposed rule change makes minor updates to conform the rule to corresponding C2 Rule 6.31(b), including allowing a TPH to change the account and subaccount field, as opposed to only the market-maker account and subaccount currently allowed, and updating the term origin code to capacity code which is both consistent with the current C2 term, as well as currently defined in the shell Rulebook and to be used in the Exchange Rules upon migration.⁶ The proposed rule retains language that provides that a change to capacity code may not be made from a customer code to any other code. The proposed rule maintains this difference between it and the corresponding C2 Rule because Cboe Options will continue to provide for customer priority upon migration,⁷ unlike C2 which does not account for

customer priority. The proposed rule change deletes current Rule 6.67(b), which lists fields TPHs may change only if they provide notice to the Exchange. Upon migration, Clearing Editor will not permit TPHs to change these fields, which is consistent with C2 Rule 6.31. If a TPH must change the series, quantity, buy or sell, or premium price, it must contact the Exchange pursuant to Rule 6.5 in the shell Rulebook (current Rule 6.25) regarding obvious errors. In light of the proposed deletion of Rule 6.67(b), the proposed rules change also removes the provision under Rule 6.67 which states that the Exchange will announce documentation requirements related to changes made through the use of CTM via a Regulatory Circular. This provision is currently in place in order for a TPH to provide to the Exchange notice and document of the any changes made pursuant to Rule 6.67(b). Because the proposed rule change removes Rule 6.67(b), this provision is no longer applicable.⁸ The proposed rule change also does not make any substantive changes to current paragraph (c) regarding changes made related to give ups, but merely moves the provision to proposed paragraph (c) and updates the language to be consistent with C2 Rule 6.31(c). The Exchange notes that the term "Designated Give Up" is also consistent with current Rule 6.21 (shell Rulebook Rule 5.10), which was recently amended to reflect such term. Finally, the proposed rule change moves current Rule 6.67.01 to proposed Rule 6.6.01 and makes only minor updates to the language to conform to C2 Rule 6.31.01. It does not make any substantive changes to this rule.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.⁹ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁰ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to,

⁵ The Exchange notes that in anticipation of migration it intends to move Rule 6.51 to Rule 6.1 without making substantive changes to the rule.

⁶ See Rule 1.1 in the shell Rulebook.

⁷ See Rule 5.32 in the shell Rulebook.

⁸ The Exchange notes that change made in the Clearing Editor will continue to be documented in the Exchange's audit trail.

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(5).

and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹¹ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The proposed rule change is intended to align the Exchange's current CTM rule and system functionality with one of the Cboe Affiliated Exchanges, C2, in order to provide a consistent technology offering across the affiliated exchanges upon the technology migration on October 7, 2019. A consistent technology offering, in turn, will simplify the technology implementation, changes and maintenance by TPHs of the Exchange that are also participants on C2. The proposed rule change does not propose to implement new or unique functionality that has not been previously filed with the Commission, found to be consistent with the Act, or is not available on Cboe Affiliated Exchanges. As a result of a consistent Clearing Editor rule and system functionality between the Exchange and C2, the proposed rule change will foster cooperation and coordination with persons engaged in facilitating transactions in securities and remove impediment to and perfect the mechanism of a free and open market and national market system by simplifying the regulatory requirements and increasing the understanding of the Exchange's operations for TPHs that are also participants on C2. The Exchange notes that the proposed rule only makes the above-mentioned minor updates in order to conform to the corresponding C2 rule; including allowing a TPH to change the account and subaccount field (as opposed to only the market-maker account and subaccount currently allowed), updating the term origin code to capacity code (which is both consistent with the C2 rule and the definition in the shell Rulebook), and removing the provision that only allows TPHs to change certain fields if they provide notice to the Exchange. The Exchange believes that these updates will provide harmonization between the functionality and rules across the affiliated exchanges, and, in turn, foster greater uniformity and less burdensome and more efficient regulatory compliance. As stated above, the proposed rule is different only to the

extent that it maintains intended differences unique to Cboe Options market-model, functionality, and/or rule text, thereby protecting investors by providing rules that clearly and properly reflect nuances between the Exchange and C2. The Exchange also notes that the proposed rule is substantially the same as the current rule. The proposed rule change makes other various non-substantive changes to the rule, largely in part to make it consistent with C2's rule. The proposed non-substantive changes will protect investors and benefit market participants by simplifying the rules, using plain English throughout the rules, and updating cross-references and paragraph lettering/numbering.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange reiterates that the proposed rule change is being proposed in the context of a technology migration of the Cboe Affiliated Exchanges. As stated, the proposed changes to the rules that reflect functionality that will be in place come October 7, 2019 provide clear rules that accurately reflect post-migration functionality upon the completion of migration. The Exchange believes the proposed rule change will benefit Exchange participants in that it will provide a consistent technology offering for TPHs by the Cboe Affiliated Exchanges. The Exchange does not believe the proposed rule change will impose any burden on intramarket competition because the proposed Clearing Editor will be available to all TPHs, both on the floor and electronically, to update executed trades on their trading date and revise them for clearing in the same manner. The Exchange also does not believe that the proposed rule change will impose any burden on intermarket competition because the basis for the proposed rule change are the rules of C2, which have previously been filed with the Commission.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) Significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act¹² and Rule 19b-4(f)(6)¹³ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-CBOE-2019-056 on the subject line.

Paper Comments

- Send paper comments in triplicate to the Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.
- All submissions should refer to File Number SR-CBOE-2019-056. 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

¹¹ *Id.*

¹² 15 U.S.C. 78s(b)(3)(A).

¹³ 17 CFR 240.19b-4(f)(6).

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-CBOE-2019-056 and should be submitted on or before October 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁴

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019-19904 Filed 9-13-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Extension:

Rule 602, SEC File No. 270-404, OMB Control No. 3235-0461

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 ("PRA") (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") is soliciting comments on the existing collection of information provided for in Rule 602 of Regulation NMS (17 CFR 240.602), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget ("OMB") for extension and approval.

Rule 602 of Regulation NMS, Dissemination of Quotations in NMS securities, contains two related

collections. The first collection of information is found in Rule 602(a).¹ This third-party disclosure requirement obligates each national securities exchange and national securities association to make available to quotation vendors for dissemination to the public the best bid, best offer, and aggregate quotation size for each "subject security," as defined under the Rule. The second collection of information is found in Rule 602(b).² This disclosure requirement obligates any exchange member and over-the-counter ("OTC") market maker that is a "responsible broker or dealer," as defined under the Rule, to communicate to an exchange or association its best bids, best offers, and quotation sizes for subject securities.³

It is anticipated that twenty-three respondents, consisting of twenty-two national securities exchanges and one national securities association, will collectively respond approximately 5,780,026,336,314 times per year pursuant to Rule 602(a) at 18.22 microseconds per response, resulting in a total annual burden of approximately 30,590 hours. It is anticipated that no respondents will have a reporting burden pursuant to Rule 602(b).⁴

Thus, the aggregate third-party disclosure burden under Rule 602 is 30,590 hours annually which is comprised of 30,590 hours relating to Rule 602(a) and 0 hours relating to Rule 602(b).

Written comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (b) the accuracy of the Commission's estimate of the burden of the proposed

collections of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of collections of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549, or send an email to: PRA_Mailbox@sec.gov.

Dated: September 11, 2019.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019-19974 Filed 9-13-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-86910; File No. SR-CBOE-2019-055]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 4.10(b) Regarding the Notice Requirement in Connection With Trading Permit Holders That Clear Market-Maker Trades

September 10, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on September 5, 2019, Cboe Exchange, Inc. (the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³ and Rule 19b-4(f)(6) thereunder.⁴ The Commission is publishing this notice to

¹ 17 CFR 242.602(a).

² 17 CFR 242.602(b).

³ Under Rule 602(b)(5), electronic communications networks ("ECNs") have the option of reporting to an exchange or association for public dissemination, on behalf of customers that are OTC market makers or exchange market makers, the best-priced orders and the full size for such orders entered by market makers on the ECN, to satisfy such market makers' reporting obligation under Rule 602(b). Since this reporting requirement is an alternative method of meeting the market makers' reporting obligation, and because it is directed to nine or fewer persons (ECNs), this collection of information is not subject to OMB review under the Paperwork Reduction Act ("PRA").

⁴ For the reporting obligation under Rule 602(b), the respondents are exchange members and OTC market makers. The Commission believes that communication of quotations through an exchange's electronic trading system effectively means that exchange members currently have no reporting burden under Rule 602(b) for these quotations. The Commission also believes that there are presently no OTC market makers that quote other than on an exchange.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴ 17 CFR 240.19b-4(f)(6).

¹⁴ 17 CFR 200.30-3(a)(12).

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

Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") proposes to amend Rule 4.10(b) regarding the notice requirement in connection with Trading Permit Holders ("TPHs") that clear Market-Maker trades. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to remove the Rule 4.10(b)(2) requirement that the Exchange issue monthly notices regarding a Trading Permit Holder's ("TPH's") proportion of market making clearing business to TPHs that clear Market-Maker trades.

Current Rule 4.10 generally provides for restrictions that the Exchange may place on "TPHs" that have failed to perform their contracts, are insolvent or in such financial or operational condition or otherwise conducting business in such a manner that they cannot be permitted to continue in business with safety to their customers or creditors or the Exchange. Current Rule 4.10(b) applies specifically to TPHs that clear Market-Maker trades. Rule 4.10(b)(2) provides that proposed Significant Business Transactions ("SBTs")⁵ of such TPHs are subject to

prior approval of the Chief Executive Officer ("CEO") or President of the Exchange, when the TPHs' Market-Maker clearance activities exceed, or would exceed, as a result of the proposed SBT: 15% of cleared Exchange Market-Maker contract volume for the most recent three months; an average of 15% of the number of Exchange registered Market-Makers as of each month and for the most recent three months; or 25% of Market-Maker gross deductions (haircuts) defined by SEC Rule 15c3-1(a)(6) or (c)(2)(x) carried by the Clearing Trading Permit Holder(s) in relation to the aggregate of such haircuts carried by all other Market-Maker clearing organizations for any month end within the most recent three months. Current Rule 4.10(b)(2) also provides that the Exchange must notify in writing each TPH that clears Market-Maker trades within 10 business days from the close of each month of that TPH's proportion of the market making clearing business, whether or not such business exceeds the parameters listed above. The Exchange now proposes to remove this Exchange notification requirement from Rule 4.10(b)(2).

In particular, the Exchange has determined that its administrative burden to proactively produce monthly notices, whether or not a Market-Maker clearing TPH's business exceeds the paragraph (b)(2) parameters, greatly exceeds the benefit in administering monthly notices due to the limited number of SBTs actually filed with the Exchange per year. The Exchange also notes that because proposed SBTs are infrequent, the receipt of monthly notices is not an integral part of a TPH's financial and operational maintenance on a month-to-month basis. If a Market-Maker clearing TPH anticipates an SBT that may require prior Exchange approval, then the TPH may contact the Exchange to determine whether the TPH exceeds the parameters. The proposed rule change makes this explicit in the rule. As a result, the Exchange believes that removing the current notice requirement from Rule 4.10(b)(2) will remove burdensome Exchange procedures without impacting the ability of a Market-Maker clearing TPH to assess its clearance activities in light of an SBT or to continue to conduct business on the Exchange.

The restrictions that Rule 4.10 imposes on TPHs will continue to apply. The Exchange notes that removing this administrative burden will also enable the Exchange to better allocate its regulatory resources, focusing on the overall monitoring of TPH business and satisfaction of these restrictions to ensure adequate financial

and operational capabilities to continue to perform contracts and otherwise conduct business safely for customers, creditors, and the Exchange. Additionally, the Exchange notes that the corresponding rules of other options exchanges currently do not contain a provision that requires such exchanges to send monthly notice to clearing members or otherwise indicate to their clearing members that they exceed, or may exceed, substantially similar criteria on the respective exchanges as a result of an SBT.⁶ Such corresponding rules of other options exchanges have previously been filed with the Commission.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.⁷ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)⁸ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)⁹ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the proposed change will remove impediments to and perfect the mechanism of a free and open market and national market system, and generally protect investors. Specifically, the Exchange believes that by removing an administrative burden in producing monthly notices for all Market-Maker clearing TPHs that greatly outweighs the benefit of such notices, due to the infrequent number of SBTs per year, the Exchange will be able to reallocate regulatory resources to focus on the overall monitoring of TPH business and

⁶ See NASDAQ Options Rules Chapter 3, Sec. 15; NASDAQ BX Options Rules Chapter 3, Sec. 15; MIAX Options Rule 306.

⁷ 15 U.S.C. 78f(b).

⁸ 15 U.S.C. 78f(b)(5).

⁹ *Id.*

⁵ See Rule 4.10(b)(1)(i)-(vii).

satisfaction of the Rule 4.10 restrictions that continue to apply to ensure adequate financial and operational capabilities to continue to perform contracts and otherwise conduct business safely for market participants, thereby protecting market participants. The Exchange also believes that the proposed rule change does not impact a Market-Maker clearing TPH's regular financial or operational maintenance or ability to assess and conduct a SBT because SBTs occur infrequently. The proposed rule change makes it clear that if a Market-Maker clearing TPH anticipates an SBT that may require prior Exchange approval, then the TPH may contact the Exchange to determine whether the TPH exceeds the parameters under Rule 4.10(b)(2). In addition to this, the Exchange believes that the proposed rule change will not present any new or unique issues for clearing TPHs because the rules of other options exchanges, which have substantially similar SBT parameters and have previously been filed with the Commission, do not require the exchanges to provide monthly notices to their members regarding their proportion of market making clearing business or otherwise indicate to their members that they exceed, or may exceed, SBT parameters.¹⁰

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In particular, the proposed rule change is not intended to address competitive issues but rather is concerned with facilitating less burdensome and more efficient regulatory administration. The Exchange does not believe that the proposed rule change will impose any intramarket competition, because all Market-Maker clearing TPHs are free to contact the Exchange to determine its standing in regard to the SBT parameters. The proposed rule change does not change the restrictions imposed on these TPHs, which will continue to apply to Market-Maker Clearing TPHs in the same manner. Further, the Exchange does not believe the proposed rule change will impose any burden on intermarket competition because the rules of other options exchanges, which have been previously filed with the Commission, provide for substantially similar parameters in connection with the impact of a clearing member's SBTs but do not contain a

provision that requires such exchanges to send monthly notice to clearing members or otherwise indicate to their clearing members that they exceed such criteria.¹¹

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act¹² and subparagraph (f)(6) of Rule 19b-4 thereunder.¹³

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or

¹¹ *Id.*

¹² 15 U.S.C. 78s(b)(3)(A).

¹³ 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.

- Send an email to rule-comments@sec.gov. Please include File Number SR-CBOE-2019-055 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-CBOE-2019-055. 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-CBOE-2019-055 and should be submitted on or before October 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁴

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019-19900 Filed 9-13-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange

¹⁴ 17 CFR 200.30-3(a)(12).

¹⁰ See *supra* note 6.

Commission, Office of FOIA Services,
100 F Street NE, Washington, DC
20549-2736

Extension:

Rule 17Ad-10, SEC File No. 270-265,
OMB Control No. 3235-0273

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 ("PRA") (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget ("OMB") a request for approval of extension of the previously approved collection of information provided for in Rule 17Ad-10 (17 CFR 240.17Ad-10), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 17Ad-10 generally requires registered transfer agents to: (1) Create and maintain current and accurate securityholder records; (2) promptly and accurately record all transfers, purchases, redemptions, and issuances, and notify their appropriate regulatory agency if they are unable to do so; (3) exercise diligent and continuous attention in resolving record inaccuracies; (4) disclose to the issuers for whom they perform transfer agent functions and to their appropriate regulatory agency information regarding record inaccuracies; (5) buy-in certain record inaccuracies that result in a physical over issuance of securities; and (6) communicate with other transfer agents related to the same issuer. These requirements assist in the creation and maintenance of accurate securityholder records, enhance the ability to research errors, and ensure the transfer agent is aware of the number of securities that are properly authorized by the issuer, thereby avoiding over issuance.

The rule also has specific recordkeeping requirements. It requires registered transfer agents to retain certificate detail that has been deleted for six years and keep current an accurate record of the number of shares or principal dollar amount of debt securities that the issuer has authorized to be outstanding. These mandatory requirements ensure accurate securityholder records and assist the Commission and other regulatory agencies with monitoring transfer agents and ensuring compliance with the rule. This rule does not involve the collection of confidential information.

There are approximately 333 registered transfer agents. We estimate that the average number of hours necessary for each transfer agent to comply with Rule 17Ad-10 is approximately 80 hours per year, which generates an industry-wide annual burden of 26,640 hours (333 times 80

hours). This burden is primarily of a recordkeeping nature but also includes a small amount of third party disclosure. At an average staff cost of \$50 per hour, the industry-wide internal labor cost of compliance (a monetization of the burden hours) is approximately \$1,332,000 per year (26,640 × \$50).

In addition, we estimate that each transfer agent will incur an annual external cost burden of \$18,000 resulting from the collection of information. Therefore, the total annual external cost on the entire transfer agent industry is approximately \$5,994,000 (\$18,000 times 333). This cost primarily reflects ongoing computer operations and maintenance associated with generating, maintaining, and disclosing or providing certain information required by the rule.

The amount of time any particular transfer agent will devote to Rule 17Ad-10 compliance will vary according to the size and scope of the transfer agent's business activity. We note, however, that at least some of the records, processes, and communications required by Rule 17Ad-10 would likely be maintained, generated, and used for transfer agent business purposes even without the rule.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: www.reginfo.gov. Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: Lindsay.M.Abate@omb.eop.gov; and (ii) Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549, or by sending an email to: PRA_Mailbox@sec.gov. Comments must be submitted to OMB within 30 days of this notice.

Dated: September 11, 2019.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019-19976 Filed 9-13-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, Washington, DC 20549-2736.

Extension:

Rule 201 and Rule 200(g) of Regulation SHO, SEC File No. 270-606, OMB Control No. 3235-0670

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) ("PRA"), the Securities and Exchange Commission ("Commission") is soliciting comments on the existing collection of information provided for in Rule 201 (17 CFR 242.201) and Rule 200(g) (17 CFR 242.200(g)) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget ("OMB") for extension and approval.

Rule 201 is a short sale-related circuit breaker rule that, if triggered, imposes a restriction on the prices at which securities may be sold short. Rule 200(g) provides that a broker-dealer may mark certain qualifying sell orders "short exempt." The information collected under Rule 201's written policies and procedures requirement applicable to trading centers, the written policies and procedures requirement of the broker-dealer provision of Rule 201(c), the written policies and procedures requirement of the riskless principal provision of Rule 201(d)(6), and the "short exempt" marking requirement of Rule 200(g) enable the Commission and self-regulatory organizations ("SROs") to examine and monitor for compliance with the requirements of Rule 201 and Rule 200(g).

In addition, the information collected under Rule 201's written policies and procedures requirement applicable to trading centers help ensure that trading centers do not execute or display any impermissibly priced short sale orders, unless an order is marked "short exempt," in accordance with the Rule's requirements. Similarly, the information collected under the written policies and procedures requirement of the broker-dealer provision of Rule 201(c) and the riskless principal provision of Rule 201(d)(6) help to ensure that broker-dealers comply with the requirements of these provisions. The information collected pursuant to the "short exempt" marking requirement of Rule 200(g) also provides an indication to a trading center when it must execute or

display a short sale order without regard to whether the short sale order is at a price that is less than or equal to the current national best bid.

It is estimated that SRO and non-SRO respondents registered with the Commission and subject to the collection of information requirements of Rule 201 and Rule 200(g) incur an aggregate annual burden of 1,621,571 hours to comply with the Rules and an aggregate annual external cost of \$220,000.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549, or send an email to: PRA_Mailbox@sec.gov.

Dated: September 11, 2019.

Jill M. Peterson,
Assistant Secretary.

[FR Doc. 2019-19975 Filed 9-13-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 10:30 a.m. on Thursday, September 19, 2019.

PLACE: The meeting will be held at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries

will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at <https://www.sec.gov>.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matters of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims;

Post argument discussion; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION:

For further information, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551-5400.

Dated: September 12, 2019.

Vanessa A. Countryman,
Secretary.

[FR Doc. 2019-20092 Filed 9-12-19; 4:15 pm]

BILLING CODE 8011-01-P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA-2019-0040]

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104-13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions, extensions, and corrections of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its

quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers. (OMB), Office of Management and

Budget, Attn: Desk Officer for SSA,
Fax: 202-395-6974, Email address:
OIRA_Submission@omb.eop.gov
(SSA), Social Security Administration,
OLCA, Attn: Reports Clearance
Director, 3100 West High Rise, 6401
Security Blvd., Baltimore, MD 21235,
Fax: 410-966-2830, Email address:
OR.Reports.Clearance@ssa.gov

Or you may submit your comments online through www.regulations.gov, referencing Docket ID Number [SSA-2019-0040].

I. The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than November 12, 2019. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. *Incorporation by Reference of Oral Findings of Fact and Rationale in Wholly Favorable Written Decisions (Bench Decision Regulation)—20 CFR 404.953 and 416.1453—0960-0694.* If an administrative law judge (ALJ) makes a wholly favorable oral decision, including all the findings and rationale for the decision for a claimant of Title II or Title XVI payments, at an administrative appeals hearing, the ALJ sends a Notice of Decision (Form HA-82), as the records from the oral hearing preclude the need for a written decision. We call this the incorporation-by-reference process. In addition, the regulations for this process state that if the involved parties want a record of the oral decision, they may submit a written request for these records. SSA collects identifying information under the aegis of Sections 20 CFR 404.953 and 416.1453 of the Code of Federal Regulations to determine how to send interested individuals written records of a favorable incorporation-by-reference oral decision made at an administrative review hearing. Since there is no prescribed form to request a written record of the decision, the involved parties send SSA their contact information and reference the hearing for which they would like a record. The respondents are applicants for Disability Insurance Benefits and SSI payments, or

their representatives, to whom SSA gave a wholly favorable oral decision under the regulations cited above.

Type of Request: Extension of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
HA-82	2,500	1	5	208	*\$10.22	**\$2,126

* We based this figure on average DI payments, as reported in SSA's disability insurance payment data.

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

2. *Request for Waiver of Special Veterans Benefits (SVB) Overpayment Recovery or Change in Repayment Rate—20 CFR 408.900–408.950—0960–0698.* Title VIII of the Act requires SSA to pay a monthly benefit to qualified World War II veterans who reside outside the United States. When an

overpayment in this SVB occurs, the beneficiary can request a waiver of recovery of the overpayment or a change in the repayment rate. SSA uses the SSA-2032-BK to obtain the information necessary to establish whether the claimant meets the waiver of recovery provisions of the overpayment, and to

determine the repayment rate if we do not waive repayment. Respondents are SVB beneficiaries who have overpayments on their Title VIII record and wish to file a claim for waiver of recovery or change in repayment rate.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
SSA-2032-BK	134	1	120	268	*\$7.67	**\$2,056

* We based this figure on average SVB payments, as per SSA's data.

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

3. *Protection and Advocacy for Beneficiaries of Social Security (PABSS)—20 CFR 435.51–435.52—0960–0768.* The PABSS projects are part of Social Security's strategy to increase the number of SSDI or SSI recipients who return to work and achieve financial independence and self-sufficiency as the result of receiving support, representation, advocacy, or other services. PABSS provides: (1) Information and advice about obtaining

vocational rehabilitation and employment services; and (2) advocacy or other services a beneficiary with a disability may need to secure, maintain, or regain gainful employment. The PABSS Annual Program Performance Report collects statistical information from each of the PABSS projects in an effort to manage and capture program performance and quantitative data. Social Security uses the information to evaluate the efficiency of the program,

and to ensure beneficiaries are receiving quality services. The project data is valuable to Social Security in its analysis of and future planning for the SSDI and SSI programs. The respondents are the 57 PABSS project sites, and recipients of SSDI and SSI programs.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
PABSS Program Grantees	57	1	60	57	*\$42.66	**\$2,432
Beneficiaries	8,284	1	30	4,142	*\$10.22	**\$42,331
Totals	8,341			4,199		**\$44,763

* We based these figures on average Computer Systems Analyst hourly salary, as reported by Bureau of Labor Statistics data, and average DI payments, as reported in SSA's disability insurance payment data.

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

4. *Methods for Conducting Personal Conferences When Waiver of Recovery of a Title II or Title XVI Overpayment Cannot Be Approved—20 CFR*

404.506(e)(3), 404.506(f)(8), 416.557(c)(3), and 416.557(d)(8)—0960–0769. SSA conducts personal conferences when we cannot approve a

waiver of recovery of a Title II or Title XVI overpayment. The Act and our regulatory citations require SSA to give overpaid Social Security beneficiaries

and SSI recipients the right to request a waiver of recovery and automatically schedule a personal conference if we cannot approve their request for waiver of overpayment. We conduct these conferences face-to-face, via telephone, or through video teleconferences. Social Security beneficiaries and SSI recipients, or their representatives, may provide documents to demonstrate they are without fault in causing the overpayment and do not have the ability

to repay the debt. They may submit these documents by completing Form SSA-632, Request for Waiver of Overpayment Recovery (OMB No. 0960-0037); Form SSA-795, Statement of Claimant or Other Person (OMB No. 0960-0045); or through a personal statement submitted by mail, telephone, personal contact, or other suitable method, such as fax or email. This information collection satisfies the requirements for request for waiver of

recovery of an overpayment, and allows individuals to pursue further levels of administrative appeal via personal conference. Respondents are Social Security beneficiaries and SSI recipients or their representatives seeking reconsideration of an SSA waiver decision.

Type of Request: Revision on an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
Title II, Personal Conference, 404.506(e)(3) and 404-506(f)(8): Submittal of documents, additional mitigating financial information, and verifications for consideration at personal conferences	30,271	1	45	22,703	* \$22.50	** \$510,818
Title XVI, Personal Conference, 416.557(c)(3) and 416-557(d)(8): Submittal of documents, additional mitigating financial information, and verifications at personal conferences. ...	51,192	1	45	38,394	* \$10.22	** \$392,378
Totals	81,463			61,097		** 903,205

* We based these figures on average U.S. citizen's hourly salary, as reported by Bureau of Labor Statistics data; and average DI payments, as reported in SSA's disability insurance payment data.

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

II. SSA submitted the information collections below to OMB for clearance. Your comments regarding these information collections would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than October 15, 2019. Individuals can obtain copies of the OMB clearance packages

by writing to OR.Reports.Clearance@ssa.gov.

1. *Application for Child's Insurance Benefits—20 CFR 404.350–404.368, 404.603, & 416.350–0960-0010.* Title II of the Act provides for the payment of monthly benefits to children of an insured retired, disabled, or deceased worker. Section 202(d) of the Act discloses the conditions and requirements the applicant must meet

when filing an application. SSA uses the information on Form SSA-4-BK to determine entitlement for children of living and deceased workers to monthly Social Security payments. Respondents are guardians completing the form on behalf of the children of living or deceased workers, or the children of living or deceased workers.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
Application for Child's Insurance Benefits/Death Claim/Paper SSA-4-BK	1,204	1	12	241	* \$22.50	** \$27,090
Application for Child's Insurance Benefits/Death Claim/Modernized Claims System (MCS) and Preliminary Claims System (PCS)	204,777	1	11	37,542	* 22.50	** 4,607,482
Application for Child's Insurance Benefits/Life Claim/Paper	3,484	1	12	697	* 22.50	** 78,390
SSA-4-BK	422,267	1	11	77,416	* 22.50	** 9,501,007
Totals	631,732			115,896		** 14,213,969

* We based this figure on average U.S. citizen's hourly salary, as reported by Bureau of Labor Statistics data.

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

2. *Request for Hearing by Administrative Law Judge—20 CFR 404.929, 404.933, 416.1429, 404.1433, 418.1350, and 42 CFR 405.722—0960–0269.* When SSA denies applicants', claimants', or beneficiaries' requests for new or continuing disability benefits or payments, the Act entitles those applicants, claimants, or beneficiaries to request a hearing to appeal the decision. To request a hearing, individuals complete Form HA–501; the associated Modernized Claims System (MCS) or SSI Claims System interview; or the

internet application (i501). SSA uses the information to determine if the individual: (1) Filed the request within the prescribed time; (2) is the proper party; and (3) took the steps necessary to obtain the right to a hearing. SSA also uses the information to determine: (1) The individual's reason(s) for disagreeing with SSA's prior determinations in the case; (2) if the individual has additional evidence to submit; (3) if the individual wants an oral hearing or a decision on the record; and (4) whether the individual has (or

wants to appoint) a representative. The respondents are Social Security disability applicants and recipients who want to appeal SSA's denial of their request for new or continued benefits for disability and non-medical hearing requests; and Medicare Part B recipients who must pay the Medicare Part B Income-Related Monthly Adjustment Amount.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
HA–501; MCS; SSI Claims System	10,325	1	10	1,721	* \$10.22	** \$17,589
i501 (Internet iAppeals)	653,318	1	5	54,443	* 10.22	** 556,407
Totals	663,643			56,164		** 573,996

* We based this figure on average DI payments, as reported in SSA's disability insurance payment data.

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

3. *Travel Expense Reimbursement—20 CFR 404.999(d) and 416.1499—0960–0434.* The Act provides for travel expense reimbursement from Federal and State agencies for claimant travel incidental to medical examinations, and to parties, their representatives, and all reasonably necessary witnesses for travel exceeding 75 miles to attend medical examinations, reconsideration

interviews, and proceedings before an administrative law judge. Reimbursement procedures require the claimant to provide: (1) A list of expenses incurred, and (2) receipts of such expenses. Federal and state personnel review the listings and receipts to verify the reimbursable amount to the requestor. The respondents are claimants for Title II

benefits and Title XVI payments, their representatives and witnesses.

Correction Notice: SSA published the incorrect burden information for this collection at 84 FR 31972, on 7/3/19. We are correcting this error here.

Type of Request: Extension of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
404.99(d) & 416.1499	60,000	1	10	10,000	* \$10.22	** \$613,200

* We based this figure on average DI payments, as reported in SSA's disability insurance payment data.

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

4. *Certificate of Coverage Request—20 CFR 404.1913—0960–0554.* The United States (U.S.) has agreements with 30 foreign countries to eliminate double Social Security coverage and taxation where, except for the provisions of the agreement, a worker would be subject to coverage and taxes in both countries. These agreements contain rules for determining the country under whose laws the worker's period of employment is covered, and to which country the

worker will pay taxes. The agreements further dictate that, upon the request of the worker or employer, the country under whose system the period of work is covered will issue a certificate of coverage. The certificate serves as proof of exemption from coverage and taxation under the system of the other country. The information we collect assists us in determining a worker's coverage and in issuing a U.S. certificate of coverage as appropriate. Per our

agreements, we ask a set number of questions to the workers and employers prior to issuing a certificate of coverage; however, our agreements with Denmark, Netherlands, Norway, and Sweden require us to ask more questions in those countries. Respondents are workers and employers wishing to establish exemption from foreign Social Security taxes.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
Requests via Letter—Individuals (minus Denmark, Netherlands, Norway, Poland & Sweden)	5,833	1	40	3,889	* \$22.50	** \$87,503
Requests via Internet—Individuals (minus Denmark, Netherlands, Norway, Poland & Sweden)	9,761	1	40	6,507	* 22.50	** 146,408
Requests via Letter—Individuals in Denmark, Netherlands, Norway, & Sweden	284	1	44	208	* 22.50	** 4,680
Requests via Letter—Individuals in Poland	16	1	41	11	* 22.50	** 248
Requests via Internet—Individuals in Denmark, Netherlands, Norway, & Sweden	427	1	44	313	* 22.50	** 7,043
Requests via Internet—Individuals in Poland	25	1	41	17	* 22.50	** 383
Requests via Letter—Employers (minus Denmark, Netherlands, Norway, Poland & Sweden)	26,047	1	40	17,365	* 22.50	** 390,713
Requests via Internet—Employers (minus Denmark, Netherlands, Norway, Poland, & Sweden)	39,096	1	40	26,064	* 22.50	** 586,440
Requests via Letter—Employers in Denmark, Netherlands, Norway, & Sweden	1,137	1	44	834	* 22.50	** 18,765
Requests via Letter—Employers in Poland	57	1	41	39	* 22.50	** 878
Requests via Internet—Employers in Denmark, Netherlands, Norway, & Sweden	1,704	1	44	1,250	* 22.50	** 28,125
Requests via Internet—Employers in Poland	86	1	41	59	* 22.50	** 1,328
Totals	84,473			56,556		** 1,272,514

* We based this figure on average U.S. citizen's hourly salary, as reported by Bureau of Labor Statistics data.

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

5. *Privacy and Disclosure of Official Records and Information; Availability of Information and Records to the Public—20 CFR 401.40(b)&(c), 401.55(b), 401.100(a), 402.130, 402.185—0960–0566.* SSA established methods for the public to: (1) Access their SSA records; (2) allow SSA to disclose records; (3) correct or amend their SSA records; (4) consent for release of their records; (5)

request records under the Freedom of Information Act (FOIA); and (6) request access to an extract of their SSN record. SSA often collects the necessary information for these requests through a written letter, with the exception of the consent for release of records, for which we use Form SSA–3288. The respondents are individuals requesting

access to, correction of, or disclosure of SSA records.

Correction Notice: SSA published this information collection as an extension on July 3, 2019 at 84 FR 3197. Since we are revising the Privacy Act Statement, this is now a revision of an OMB-approved information collection.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
Access to Records	10,000	1	11	1,833	* \$22.50	** \$41,243
Designating a Representative for Disclosure of Records	3,000	1	2	6,000	* 22.50	** 135,000
Amendment of Records	100	1	10	17	* 22.50	** 383
Consent of Release of Records	3,000,760	1	3	150,038	* 22.50	** 3,375,855
FOIA Requests for Records	15,000	1	5	1,250	* 22.50	** 28,125
Respondents who request access to an extract of their SSN record	10	1	8.5	1	* 22.50	** 22.50
Totals	3,028,870			159,139		** 3,580,629

* We based these figures on average U.S. citizen's hourly salary, as reported by Bureau of Labor Statistics data.

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

6. *Disability Report—Child—20 CFR 416.912–0960–0577.* Sections 223(d)(5)(A) and 1631(e)(1) of the Act require SSI claimants to furnish medical and other evidence to prove they are disabled. SSA uses Form SSA–3820 to collect various types of information about a child's condition from treating

sources or other medical sources of evidence. The State Disability Determination Services evaluators use the information from Form SSA–3820 to develop medical and school evidence, and to assess the alleged disability. The information, together with medical evidence, forms the evidentiary basis

upon which SSA makes its initial disability evaluation. The respondents are claimants seeking SSI childhood disability payments.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
SSA–3820	177,572	1	90	266,358	10.22	** 1,814,786
EDCS	1,000	1	120	2,000	10.22	** 10,220
i3820	176,572	1	120	353,144	10.22	** 1,804,566
Totals	355,144			621,502		** 3,629,572

* We based this figure on average DI payments, as reported in SSA's disability insurance payment data.

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

7. *Request for Reconsideration—20 CFR 404.907–404.921, 416.1407–416.1421, 408.1009, and 418.1325–0960–0622.* The Act states those individuals who are dissatisfied with the results of an initial determination regarding their Title II disability; Title XVI disability (SSI); Title VIII (SVB); or Title XVIII (Medicare benefits), can request a reconsideration hearing.

Individuals use Form SSA–561–U2; the associated MCS or SSI Claims System interview; or the internet application (i561) to initiate a request for reconsideration of a denied claim. SSA uses the information to document the request and to determine an individual's eligibility or entitlement to Social Security benefits (Title II); SSI payments (Title XVI); Special Veterans Benefits

(Title VIII); Medicare (Title XVIII); and for initial determinations regarding Medicare Part B income-related premium subsidy reductions. The respondents are applicants, claimants, beneficiaries, or recipients filing for reconsideration of an initial determination.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
SSA–561 and Modernized Claims System (MCS)	330,370	1	8	40,049	* 10.22	** 409,301
I561 (Internet iAppeals)	1,161,300	1	5	96,775	* 10.22	** 989,041
Totals	1,461,670			136,824		** 1,398,342

* We based this figure on average DI payments, as reported in SSA's disability insurance payment data.

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

8. *Request to Withdraw a Hearing Request; Request to Withdraw an Appeals Council Request for Review; and Administrative Review Process for Adjudicating Initial Disability Claims—20 CFR Parts 404, 405, and 416–0960–0710.* Claimants have a statutory right under the Act and current regulations to apply for SSDI benefits or SSI payments. SSA collects information at each step of the administrative process to adjudicate

claims fairly and efficiently. SSA collects this information to establish a claimant's right to administrative review, and determine the severity of the claimant's alleged impairments. SSA uses the information we collect to determine entitlement or continuing eligibility to SSDI benefits or SSI payments, and to enable appeals of these determinations. In addition, SSA collects information on Forms HA–85

and HA–86 to allow claimants to withdraw a hearing request or an Appeals Council review request. The respondents are applicants for Title II SSDI or Title XVI SSI benefits; their appointed representatives; legal advocates; medical sources; and schools.

Type of Request: Revision of an OMB-approved information collection.

20 CFR section No.	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
404.961, 416.1461, 405.330, and 405.366	12,220	1	20	4,073	10.22	** 41,626
404.950, 416.1450, and 405.332	1,040	1	20	347	10.22	** 3,546
404.949 and 416.1449	2,868	1	60	2,868	10.22	** 29,311
405.334	20	1	60	20	10.22	** 204
404.957, 416.1457, and 405.380	21,041	1	10	3,507	10.22	** 35,842
405.381	37	1	30	19	10.22	** 194
405.401	5,310	1	10	885	10.22	** 9,045
404.971 and 416.1471 (HA-85; HA-86)	1,606	1	10	268	10.22	** 2,739
404.982 and 416.1482	1,687	1	30	844	10.22	** 8,626
404.987 & 404.988 and 416.1487 & 416.1488 and 405.601	12,425	1	30	6,213	10.22	** 63,497
404.1740(b)(1)	150	1	2	5	22.50	** 113
416.1540(b)(1)	150	1	2	5	22.50	** 113
404.1512, 404.1740(c)(4), 416.912, and 416.1540(c)(4)	150	1	2	5	22.50	** 113
405.372(c)	5,310	1	10	885	10.22	** 9,045
405.1(b)(5) and 405.372(b)	833	1	30	417	10.22	** 4,262
405.505	833	1	30	417	10.22	** 4,262
405.1(c)(2)	5,310	1	10	885	10.22	** 9,045
405.20	5,310	1	10	885	10.22	** 9,045
Totals	76,300			22,548		** 230,628

* We based these figures on average DI payments, as reported in SSA's disability insurance payment data, and average U.S. citizen's hourly salary, as reported by Bureau of Labor Statistics data.

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

9. *Request for Accommodation in Communication Method—0960-0777.* SSA allows disabled or impaired Social Security applicants, beneficiaries, recipients, and representative payees to choose one of seven alternative methods of communication they want SSA to use when we send them benefit notices and other related communications. The seven alternative methods we offer are: (1) Standard print notice by first-class mail; (2) standard print mail with a follow-up telephone call; (3) certified mail; (4) Braille; (5) Microsoft Word file on data CD; (6) large print (18-point font); or (7) audio CD. However,

respondents who want to receive notices from SSA through a communication method other than the seven methods listed above must explain their request to us. Those respondents use Form SSA-9000 to: (1) Describe the type of accommodation they want; (2) disclose their condition necessitating the need for a different type of accommodation; and (3) explain why none of the seven methods described above are sufficient for their needs. SSA uses Form SSA-9000 to determine, based on applicable law and regulation, whether to grant the respondents' requests for an

accommodation based on their impairment or disability. SSA collects this information electronically through either an in-person interview or a telephone interview during which the SSA employee keys in the information on our iAccommodate Intranet screens. The respondents are disabled or impaired Social Security applicants, beneficiaries, recipients, and representative payees who ask SSA to send notices and other communications in an alternative method besides the seven modalities we currently offer.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
SSA-9000/iAccommodate	5,000	1	20	1,667	* \$10.22	** \$51,100

* We based this figure on average DI payments, as reported in SSA's disability insurance payment data.

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

10. *Report of Adult Functioning-Employer—20 CFR 404.1512 and 416.912—0960-0805.* Section 205 (a), 223(d)(5)(A), 1631(d)(1), and 1631(e)(1) of the Act require claimants' applying for SSDI benefits or SSI payments to provide SSA with medical and other

evidence of their disability. 20 CFR 404.1512 and 20 CFR 416.912 of the Code of Federal Regulations provides detailed requirements of the types of evidence SSDI beneficiaries and SSI claimants must provide showing how their impairment(s) affect their ability to

work (e.g., evidence of age, education and training, work experience, daily activities, efforts to work, and any other evidence). Past employers familiar with the claimant's ability to perform work activities completes Form SSA-385-BK, Report of Adult Functioning-Employer

to provide SSA with information about the employees day-to-day functioning in the work setting. SSA and Disability Determination Services use the

information Form SSA-3385-BK collects as the basis to determine eligibility or continued eligibility for

disability benefits. The respondents are claimants' past employers.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars)*	Total annual opportunity cost (dollars)**
SSA-3385-BK	3,601	1	20	1,200	*\$22.50	**\$27,000

* We based these figures on average U.S. citizen's hourly salary, as reported by Bureau of Labor Statistics data.

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

Dated: September 9, 2019.

Naomi Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2019-19910 Filed 9-13-19; 8:45 am]

BILLING CODE 4191-02-P

DEPARTMENT OF STATE

[Public Notice:10875]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: “Flesh and Blood: Italian Masterpieces From the Capodimonte Museum” Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition “Flesh and Blood: Italian Masterpieces from the Capodimonte Museum,” imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to agreements with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit objects at the Seattle Art Museum, Seattle, Washington, from on or about October 17, 2019, until on or about January 26, 2020; at the Kimbell Art Museum, Fort Worth, Texas, from on or about March 1, 2020, until on or about June 14, 2020; and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Paralegal Specialist, Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6471; email: section2459@state.gov). The mailing address is U.S. Department of State, L/PD, SA-5, Suite 5H03, Washington, DC 20522-0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made

pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236-3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2019-19995 Filed 9-13-19; 8:45 am]

BILLING CODE 4710-05-P

DEPARTMENT OF STATE

[Public Notice: 10877]

Notice of Determinations: Culturally Significant Objects Imported for Exhibition—Determinations: “Félix Vallotton: Painter of Disquiet” Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition “Félix Vallotton: Painter of Disquiet,” imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Metropolitan Museum of Art, New York, New York, from on or about October 29, 2019, until on or about January 26, 2020, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Paralegal Specialist, Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6471; email: section2459@state.gov). The mailing

address is U.S. Department of State, L/PD, SA-5, Suite 5H03, Washington, DC 20522-0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236-3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2019-19996 Filed 9-13-19; 8:45 am]

BILLING CODE 4710-05-P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 1020 (Sub-No. 2X)]

East Penn Railroad, LLC—Discontinuance of Service and Lease Operations—in Northeast Philadelphia, Pa.

East Penn Railroad, LLC (ESPN), has filed a verified notice of exemption under 49 CFR 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* to discontinue service and terminate its lease operations over approximately 1.8 miles of rail line owned by Norfolk Southern Railway Company (NSR) between milepost VE 0.00 and milepost VE 1.80 in Northeast Philadelphia, Pa. (the Line). The Line traverses U.S. Postal Service Zip Codes 19004 and 19127.

ESPN has certified that: (1) It has not moved any local or overhead traffic over the Line for at least two years; (2) overhead traffic, if there were any, could be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local

government entity acting on behalf of such user) regarding cessation of service over the Line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the two-year period; and (4) the applicable requirements at 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

Any employee of ESPN adversely affected by the discontinuance of service shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) ¹ to subsidize continued rail service has been received, this exemption will be effective on October 16, 2019, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues and formal expressions of intent to file an OFA to subsidize continued rail service under 49 CFR 1152.27(c)(2) ² must be filed by September 26, 2019. ³ Petitions for reconsideration must be filed by October 7, 2019, with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to ESPN's representatives, William A. Mullins and Crystal M. Zorbaugh, Baker & Miller PLLC, 2401 Pennsylvania Ave. NW, Suite 300, Washington, DC 20037.

If the verified notice contains false or misleading information, the exemption is void ab initio.

Board decisions and notices are available at www.stb.gov.

Decided: September 11, 2019.

¹ Persons interested in submitting an OFA to subsidize continued rail service must first file a formal expression of intent to file an offer, indicating the intent to file an OFA for subsidy and demonstrating that they are preliminarily financially responsible. See 49 CFR 1152.27(c)(2)(i).

² The filing fee for OFAs can be found at 49 CFR 1002.2(f)(25).

³ Because this is a discontinuance proceeding and not an abandonment, trail use/rail banking and public use conditions are not appropriate. Because there will be an environmental review during abandonment, this discontinuance does not require environmental review.

By the Board, Allison C. Davis, Director, Office of Proceedings.

Andrea Pope-Matheson,
Clearance Clerk.

[FR Doc. 2019–19938 Filed 9–13–19; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2018–0106 Notice 1]

Daimler Vans USA, LLC, Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: Daimler Vans USA, LLC, (Daimler Vans) on behalf of Daimler AG (DAG) has determined that certain model year (MY) 2016–2018 Mercedes-Benz Metris vans do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 110, *Tire Selection and Rims and Motor Home/ Recreation Vehicle Trailer Load Carrying Capacity Information for Motor Vehicles with a GVWR of 4,536 kilograms (10,000 pounds) or Less*. Daimler Vans filed a noncompliance report dated October 24, 2018, and later amended it on November 9, 2018. Daimler Vans also petitioned NHTSA on November 9, 2018, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This document announces receipt of the Daimler Vans petition.

DATES: The closing date for comments on the petition is October 16, 2019.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket number cited in the title of this notice and may be submitted by any of the following methods:

- **Mail:** Send comments by mail addressed to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- **Hand Delivery:** Deliver comments by hand to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except for Federal Holidays.

- **Electronically:** Submit comments electronically by logging onto the Federal Docket Management System (FDMS) website at <https://www.regulations.gov/>. Follow the online instructions for submitting comments.

- Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to <https://www.regulations.gov/>, including any personal information provided.

All comments and supporting materials received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the fullest extent possible.

When the petition is granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All comments, background documentation, and supporting materials submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the internet at <https://www.regulations.gov/> by following the online instructions for accessing the dockets. The docket ID number for this petition is shown in the heading of this notice.

DOT's complete Privacy Act Statement is available for review in a **Federal Register** notice published on April 11, 2000, (65 FR 19477–78).

SUPPLEMENTARY INFORMATION:

I. **Overview:** Daimler Vans has determined that certain MY 2016–2018 Mercedes-Benz Metris vans do not fully comply with FMVSS No. 110, *Tire Selection and Rims and Motor Home/ Recreation Vehicle Trailer Load Carrying Capacity Information for Motor Vehicles with a GVWR of 4,536 kilograms (10,000 pounds) or Less* (49 CFR 571.110). Daimler Vans filed a noncompliance report dated October 24, 2018, and later amended it on November 9, 2018, pursuant to 49 CFR part 573, *Defect and Noncompliance*

Responsibility and Reports. Daimler Vans also petitioned NHTSA on November 9, 2018, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance*.

This notice of receipt, of the Daimler Vans petition, is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercises of judgment concerning the merits of the petition.

II. *Vehicles Involved:* Approximately 24,438 MY 2016–2018 Mercedes Benz-Metris vans, manufactured between June 1, 2016, and September 28, 2018, are potentially involved.

III. *Noncompliance:* The purpose of FMVSS No. 110 is to ensure that each vehicle is equipped with tires and rims that are appropriate to carry up to the maximum weight of the vehicle in order to prevent vehicle overloading. Manufacturers are permitted to install passenger car tires on an MPV, truck, bus or trailer. However, when passenger car tires are used in one of these other light vehicle applications, paragraph S4.2.2.2 of FMVSS No. 110, provides that each tire's maximum load rating is to be divided by 1.10 before the manufacturer determines the maximum load ratings of the tires fitted to each axle. Specifically, the subject vehicles were certified with a maximum load rating of 775 kg (1708 pounds) per tire or 1,550 kg (3417 pounds) combined per axle, however, after dividing the maximum load rating by 1.10, the tires on the subject vehicles have a maximum load rating of 750 kg (1653 pounds) per tire and 1500 kg (3307 pounds) per axle—values below the GAWR for the front and rear axles.

IV. *Rule Requirements:* Paragraph S4.2.2.2 of FMVSS No. 110 includes the requirement relevant to this petition. When passenger car tires are installed on an MPV, truck, bus, or trailer, each tire's load rating is reduced by dividing it by 1.10 before determining, under paragraph S4.2.2.1, the sum of the maximum load ratings of the tires fitted to an axle.

V. *Summary of Petition:* Daimler Vans described the subject noncompliance and stated its belief that the noncompliance is inconsequential as it relates to motor vehicle safety.

In support of its petition, Daimler Vans USA, LLC submitted the following reasoning:

1. There is no safety risk posed with this noncompliance because the tires are

designed to carry significantly more than the GAWR listed on the certification label.

2. The Metris vans also have installed the same tire size as the Metris vans sold in Europe that have the same axle weight ratings and those vehicles have performed without incident for years.

3. Despite the discrepancy in calculating the maximum load rating, the Metris vans are more than able to accommodate additional weight loaded onto the vehicle. Per the specifications provided by the tire supplier, based on the tire's load index rating of 101, each tire, in fact, has a maximum load rating of 825 kg (1,818 pounds) per tire and a combined maximum load rating of 1,650 kg (3,637 pounds) per axle. Thus, the tires were designed and manufactured to safely and effectively manage weights that are well beyond the GAWR for each axle.

4. The GAWR listed on the vehicle certification label is accurate so that a consumer relying on and following the values for the front and rear GAWR, for purposes of vehicle loading, would not be at risk of overloading the axles.

5. The tires on the Metris vans have a payload reserve of 6.5 percent at a load of 1,550 kg per axle, which is slightly below the payload reserve of 10 percent specified by FMVSS No. 110. Moreover, the tire pressure specified for each tire on the Metris Van is at least 11% higher (tire pressure reserve) than the ETRTO recommended tire pressure. This tire pressure reserve reduces the stress on the tire, due to reduced deflection of the tire under load.

6. Further, the Metris vans are equipped with a standard tire pressure monitoring system (TPMS) that is compliant with FMVSS No. 138. Depending on the severity of the loss of tire pressure, the Metris vans display one of three specialized TPMS warnings in the instrument panel advising the operator of the loss of pressure and how quickly the operator should take corrective action. If the tires were to experience a loss of tire pressure, the driver would be alerted to this condition and could take appropriate measures. Thus, if there were to be a loss of tire pressure, consistent with the standard, the TPMS system would warn the operator.

7. After identifying the discrepancy in the values listed on the tire and loading information placard, DAG reviewed what, if any, impact there could be on various vehicle systems that could potentially be affected by the discrepancy. This review considered the effect on steering, breaking, axle strength, and crashworthiness if the operator loaded the vehicle to the

maximum amount listed on the tire and loading information placard. As a result of the review, DAG was able to confirm that the discrepancy will not adversely impact any of these systems or otherwise diminish the performance or crashworthiness of the Metris vans.

8. DAG is not aware of any consumer complaints or reports of accidents or injuries related to overloading the vehicles that could reasonably be related to not derating the reinforced passenger car tires prior to certification. In addition, Metris vans sold in Europe are equipped with tires that are the same size and the vehicles have the same axle weight ratings. The European vehicles have similarly performed without incident.

9. The agency has previously granted petitions for inconsequential noncompliance involving similar inconsistencies involving tire maximum load ratings. In 2017, the agency granted a petition for inconsequential noncompliance where a manufacturer had incorrectly overstated the maximum occupant and cargo weight on the tire and loading information placard, by a total of 30 kg. Although on its face, this discrepancy would have appeared to have led consumers to potentially overload the vehicle, the agency concluded that when the vehicle was loaded to the value listed on the placard, the specific tires installed on the vehicles were nonetheless technically capable of handling the overstated weight and cargo. In this instance, for one vehicle variation, the maximum loads were below the GAWR and gross vehicle weight rating (GVWR) and for another vehicle variation, the maximum loads were "essentially at the certified GAWR and GVWR values." The agency concluded that the tires were "more than adequate" to manage the additional vehicle and cargo weight and that the vehicles could safely manage the additional weight without overload concerns. See 82 FR 33547 (July 20, 2017) (grant of petition for inconsequential noncompliance by Mercedes-Benz USA, LLC).

10. The noncompliance at issue here is similar to the above petition. In this case, there is also little concern of vehicle overloading because the specifications for the tires installed on the Metris vans are technically capable of managing the additional weight even without the reinforced passenger car tires having been derated.

Daimler Vans concluded by expressing the belief that the subject noncompliance is inconsequential as it relates to motor vehicle safety, and that its petition to be exempted from providing notification of the

noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

The Daimler Vans complete petition and all supporting documents are available by logging onto the Federal Docket Management System (FDMS) website at <https://www.regulations.gov> and following the online search instructions to locate the docket number listed in the title of this notice.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject vehicles that Daimler Vans no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after Daimler Vans notified them that the subject noncompliance existed.

Authority: 49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8.

Otto G. Matheke III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2019-19918 Filed 9-13-19; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Issuance of Russia-Related Directive Pursuant to Executive Order 13883 of August 1, 2019

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Issuance of directive.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) has issued a Russia-Related Directive under Executive Order 13883 of August 1, 2019.

DATES: OFAC's action described in this notice was effective on August 26, 2019.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, 202-622-2420; Assistant Director for Licensing, 202-622-2480;

Assistant Director for Regulatory Affairs, 202-622-4855; or Assistant Director for Sanctions Compliance & Evaluation, 202-622-2490.

SUPPLEMENTARY INFORMATION: On August 6, 2018, the Secretary of State, acting pursuant to delegated authority under section 306(a) of the Chemical and Biological Weapons Control and Warfare Elimination Act of 1991, as amended, 22 U.S.C. 5601 *et seq.* (CBW Act), determined that the Government of the Russian Federation (Russia) had used chemical weapons in violation of international law or had used lethal chemical weapons against its own nationals. On August 27, 2018, pursuant to his August 6, 2018 determination, the Secretary of State imposed an initial round of sanctions on Russia (83 FR 43723, August 27, 2018). Section 307(b)(1) of the CBW Act requires the imposition of additional sanctions on Russia unless, within three months after making such a determination, the Secretary of State finds Russia has met certain conditions. On November 6, 2018, the Secretary of State found that Russia had not met the required conditions. On August 2, 2019, the Secretary of State selected three additional sanctions to impose on Russia (84 FR 44671, August 26, 2019).

On August 1, 2019, the President, invoking the authority of, *inter alia*, the International Emergency Economic Powers Act (50 U.S.C. 1701-1706) (IEEPA) and the CBW Act, issued Executive Order (E.O.) 13883 ("Administration of Proliferation Sanctions and Amendment of Executive Order 12851") (84 FR 38113, August 5, 2019). The President issued E.O. 13883 in order to take additional steps with respect to the national emergency described and declared in Executive Order 12938 of November 14, 1994, as amended by and relied on for additional steps in subsequent Executive Orders.

In E.O. 13883, the President directed the Secretary of the Treasury, in consultation with the Secretary of State, to take the following actions when necessary to implement certain sanctions set forth in E.O. 13883 and section 307(b)(2) of the CBW Act selected for imposition on a country by the President or the Secretary of State pursuant to section 307(b)(1) of the CBW Act: (i) Oppose, in accordance with section 701 of the International Financial Institutions Act (22 U.S.C. 262d), the extension of any loan or financial or technical assistance to that country by international financial institutions; and (ii) prohibit any United States bank from making any loan or providing any credit to the government

of that country, except for loans or credits for the purpose of purchasing food or other agricultural commodities or products.

Accordingly, on August 2, 2019, pursuant to the Secretary of State's August 2, 2019 decision to impose additional sanctions on Russia, E.O. 13883, and the Weapons of Mass Destruction Proliferators Sanctions Regulations, 31 CFR 544.802, the Director of OFAC issued the Russia-Related Directive Under Executive Order 13883 of August 1, 2019 (CBW Act Directive). OFAC made the CBW Act Directive available on its website on August 3, 2019. OFAC is publishing the CBW Act Directive in the **Federal Register**, updated to include the number of the Executive Order of August 1, 2019.

Russia-Related Directive Under Executive Order of August 1, 2019 ("CBW Act Directive")

Pursuant to sections 1(a)(ii), 1(b), and 5 of Executive Order 13883 of August 1, 2019 "Administration of Proliferation Sanctions and Amendment of Executive Order 12851" (the "Order") and 31 CFR 544.802, and following the Secretary of State's selection of the sanction related to bank loans pursuant to delegated authority under section 307(b) of the Chemical and Biological Weapons Control and Warfare Elimination Act of 1991, as amended (22 U.S.C. 5605(b)), the Director of the Office of Foreign Assets Control has determined, in consultation with the Department of State, that the following activities by a U.S. bank, as defined below, including foreign branches, are prohibited, except to the extent provided by law or unless licensed or otherwise authorized by the Office of Foreign Assets Control: (1) Participation in the primary market for non-ruble denominated bonds issued by the Russian sovereign, as defined below, after August 26, 2019; and (2) lending non-ruble denominated funds to the Russian sovereign, as defined below, after August 26, 2019.

For purposes of this Directive, the term "U.S. bank" means, consistent with the Order and 31 CFR 544.311, any entity organized under the laws of the United States or any jurisdiction within the United States (including its foreign branches), or any entity in the United States, that is engaged in the business of accepting deposits, making, granting, transferring, holding, or brokering loans or credits, or purchasing or selling foreign exchange, securities, commodity futures, or options, or procuring purchasers and sellers thereof, as principal or agent. The term "U.S. bank" includes but is not limited to

depository institutions, banks, savings banks, trust companies, securities brokers and dealers, commodity futures and options brokers and dealers, forward contract and foreign exchange merchants, securities and commodities exchanges, clearing corporations, investment companies, employee benefit plans, and U.S. holding companies, U.S. affiliates, or U.S. subsidiaries of any of the foregoing. This term includes those branches, offices and agencies of foreign financial institutions that are located in the United States and otherwise meet the definition of "U.S. bank" used in this Directive, but not such institutions' foreign branches, offices, or agencies.

Furthermore, for purposes of this Directive, the term "Russian sovereign" means any ministry, agency, or sovereign fund of the Russian Federation, including the Central Bank of Russia, the National Wealth Fund, and the Ministry of Finance of the Russian Federation. This term does not include state-owned enterprises of the Russian Federation.

Except to the extent otherwise provided by law or unless licensed or otherwise authorized by the Office of Foreign Assets Control, the following are also prohibited: (1) Any transaction that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions contained in this Directive; and (2) any conspiracy formed to violate any of the prohibitions in this Directive.

August 2, 2019

Dated: September 10, 2019.

Andrea Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2019-19890 Filed 9-13-19; 8:45 am]

BILLING CODE 4810-AL-P

DEPARTMENT OF VETERANS AFFAIRS

Change of Publication Manner for Invention Licenses

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Currently, the Department of Veterans Affairs (VA) publishes notices of prospective exclusive, co-exclusive, or partially-exclusive domestic or foreign licenses of Government-owned inventions in the **Federal Register**. VA is announcing that it will begin publishing such notices at the Federal Laboratory Consortium for Technology Transfer (FLC) Business website (<http://www.federallabs.org/licenses-list>), providing opportunity for filing written objections within at least a 15-day period.

FOR FURTHER INFORMATION CONTACT: Dr. John J. Kaplan, Ph.D., J.D., Director, VA Technology Transfer Program (10X2TT), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420; by email at John.Kaplan@va.gov, or by phone at (202) 632-7271 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: Pursuant to 37 CFR 404.7(a)(1)(i) and (b)(1)(i), an exclusive, co-exclusive, or partially-exclusive foreign license, may be granted on Government owned inventions only if notice of a prospective license has been published in the **Federal Register** or other appropriate manner, providing opportunity for filing written objections within at least a 15-day period. VA provides notice that it will publish future notices of prospective exclusive, co-exclusive, or partially-exclusive domestic or foreign licenses on FLC Business website (<http://www.federallabs.org/licenses-list>), providing opportunity for filing written objections within at least a 15-day period.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert L. Wilkie, Secretary, Department of Veterans Affairs, approved this document on September 5, 2019, for publication.

Dated: September 5, 2019.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

[FR Doc. 2019-19952 Filed 9-13-19; 8:45 am]

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Part II

Environmental Protection Agency

40 CFR Part 63

National Emission Standards for Hazardous Air Pollutants: Lime
Manufacturing Plants Residual Risk and Technology Review; Proposed
Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA-HQ-OAR-2017-0015; FRL-9998-85-OAR]

RIN 2060-AT08

National Emission Standards for Hazardous Air Pollutants: Lime Manufacturing Plants Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing the results of the residual risk and technology reviews (RTR) for the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Lime Manufacturing Plants. We are proposing to find that risks due to emissions of air toxics from this source category are acceptable and that the current NESHAP provides an ample margin of safety to protect public health. Under the technology review, we are proposing to find that there are no developments in practices, processes, or control technologies that necessitate revision of the standards. We are proposing to amend provisions addressing periods of startup, shutdown, and malfunction (SSM) and to add provisions regarding electronic reporting.

DATES: *Comments.* Comments must be received on or before October 31, 2019. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before October 16, 2019.

Public hearing. If anyone contacts us requesting a public hearing on or before September 23, 2019, we will hold a hearing. Additional information about the hearing, if requested, will be published in a subsequent **Federal Register** document and posted at <https://www.epa.gov/stationary-sources-air-pollution/lime-manufacturing-plants-national-emission-standards-hazardous-air>. See **SUPPLEMENTARY INFORMATION** for information on requesting and registering for a public hearing.

ADDRESSES: You may send comments, identified by Docket ID No. EPA-HQ-OAR-2017-0015, by any of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov/> (our

preferred method). Follow the online instructions for submitting comments.

- *Email:* a-and-r-docket@epa.gov. Include Docket ID No. EPA-HQ-OAR-2017-0015 in the subject line of the message.

- *Fax:* (202) 566-9744. Attention Docket ID No. EPA-HQ-OAR-2017-0015.

- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA-HQ-OAR-2017-0015, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

- *Hand/Courier Delivery:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m.–4:30 p.m., Monday–Friday (except federal holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to <https://www.regulations.gov/>, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact Jim Eddinger, Sector Policies and Programs Division (D243-01), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-5426; fax number: (919) 541-4991; and email address: edding.jim@epa.gov. For specific information regarding the risk modeling methodology, contact James Hirtz, Health and Environmental Impacts Division (C539-02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-0881; fax number: (919) 541-0840; and email address: hirtz.james@epa.gov. For questions about monitoring and testing requirements, contact Mike Ciolek, Sector Policies and Programs Division (D243-05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-4921; fax number: (919) 541-4991; and email address: ciolek.mike@epa.gov. For information about the applicability of the NESHAP to a particular entity, contact Sara Ayres, Office of Enforcement and Compliance

Assurance, U.S. Environmental Protection Agency, USEPA Region 5 (Mail Code E-19), 77 West Jackson Boulevard, Chicago, Illinois 60604; telephone number: (312) 353-6266; and email address: ayres.sara@epa.gov.

SUPPLEMENTARY INFORMATION:

Public hearing. Please contact Adrian Gates at (919) 541-4860 or by email at gates.adrian@epa.gov to request a public hearing, to register to speak at the public hearing, or to inquire as to whether a public hearing will be held.

Docket. The EPA has established a docket for this rulemaking under Docket ID No. EPA-HQ-OAR-2017-0015. All documents in the docket are listed in *Regulations.gov*. Although listed, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *Regulations.gov* or in hard copy at the EPA Docket Center, Room 3334, WJC West Building, 1301 Constitution Avenue NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the EPA Docket Center is (202) 566-1742.

Instructions. Direct your comments to Docket ID No. EPA-HQ-OAR-2017-0015. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <https://www.regulations.gov/>, including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <https://www.regulations.gov/> or email. This type of information should be submitted by mail as discussed below.

The EPA may publish any comment received to its public docket. 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, 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>.

The <https://www.regulations.gov/> website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through <https://www.regulations.gov/>, 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. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at <https://www.epa.gov/dockets>.

Submitting CBI. Do not submit information containing CBI to the EPA through <https://www.regulations.gov/> or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in *Instructions* above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2. Send or deliver information identified as CBI only to the following address: OAQPS Document Control

Officer (C404-02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA-HQ-OAR-2017-0015.

Preamble acronyms and abbreviations. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

AEGL acute exposure guideline level
 AERMOD air dispersion model used by the HEM-3 model
 CAA Clean Air Act
 CalEPA California EPA
 CBI Confidential Business Information
 CFR Code of Federal Regulations
 D/F dioxins and furans
 ECHO Enforcement and Compliance History Online
 EPA Environmental Protection Agency
 ERPG emergency response planning guideline
 ERT Electronic Reporting Tool
 g/dscm grams per dry standard cubic meter
 HAP hazardous air pollutant(s)
 HCl hydrochloric acid
 HEM-3 Human Exposure Model, Version 1.5.5
 HF hydrogen fluoride
 HI hazard index
 HQ hazard quotient
 IRIS Integrated Risk Information System
 km kilometer
 lb/tsf pounds per ton of stone feed
 MACT maximum achievable control technology
 mg/m³ milligrams per cubic meter
 MIR maximum individual risk
 NAAQS National Ambient Air Quality Standards
 NAICS North American Industry Classification System
 NEI National Emissions Inventory
 NESHAP national emission standards for hazardous air pollutants
 NTTAA National Technology Transfer and Advancement Act
 OAQPS Office of Air Quality Planning and Standards
 OECA Office of Enforcement and Compliance Assurance
 OMB Office of Management and Budget
 PB-HAP hazardous air pollutants known to be persistent and bio-accumulative in the environment
 PM particulate matter
 POM polycyclic organic matter
 ppm parts per million
 PSH processed stone handling system
 REL reference exposure level
 RFA Regulatory Flexibility Act
 RfC reference concentration
 RTR residual risk and technology review
 SAB Science Advisory Board
 SSM startup, shutdown, and malfunction
 TOSHI target organ-specific hazard index
 tpy tons per year
 TRIM.FaTE Total Risk Integrated Methodology.Fate, Transport, and Ecological Exposure model
 UF uncertainty factor

UMRA Unfunded Mandates Reform Act
 URE unit risk estimate

Organization of this document. The information in this preamble is organized as follows:

- I. General Information
 - A. Does this action apply to me?
 - B. Where can I get a copy of this document and other related information?
- II. Background
 - A. What is the statutory authority for this action?
 - B. What is this source category and how does the current NESHAP regulate its HAP emissions?
 - C. What data collection activities were conducted to support this action?
 - D. What other relevant background information and data are available?
- III. Analytical Procedures and Decision-Making
 - A. How do we consider risk in our decision-making?
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- IV. Analytical Results and Proposed Decisions
 - A. What are the results of the risk assessment and analyses?
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 - D. What other actions are we proposing?
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- V. Summary of Cost, Environmental, and Economic Impacts
 - A. What are the affected sources?
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- VI. Request for Comments
- VII. Submitting Data Corrections
- VIII. Statutory and Executive Order Reviews
 - A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
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 - F. Executive Order 13132: Federalism
 - G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
 - H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
 - I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
 - J. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

I. General Information

A. Does this action apply to me?

Table 1 of this preamble lists the NESHAP and associated regulated industrial source category that is the subject of this proposal. Table 1 is not intended to be exhaustive, but rather

provides a guide for readers regarding the entities that this proposed action is likely to affect. The proposed standards, once promulgated, will be directly applicable to the affected sources. Federal, state, local, and tribal government entities would not be affected by this proposed action. As defined in the *Initial List of Categories of Sources Under Section 112(c)(1) of the Clean Air Act Amendments of 1990* (see 57 FR 31576, July 16, 1992) and

Documentation for Developing the Initial Source Category List, Final Report (see EPA-450/3-91-030, July 1992), the Lime Manufacturing source category is any facility engaged in producing high calcium lime, dolomitic lime, and dead-burned dolomite. However, lime manufacturing plants located at pulp and paper mills or at beet sugar factories are not included in the source category (see 69 FR 397, January 5, 2004).

TABLE 1—NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS PROPOSED ACTION

Source category	NESHAP	NAICS code ¹
Lime Manufacturing	Lime Manufacturing Plants	32741, 33111, 3314, 327125

¹ North American Industry Classification System.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this action is available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at <https://www.epa.gov/lime-manufacturing-plants-national-emission-standards-hazardous-air>. Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the proposal and key technical documents at this same website. Information on the overall RTR program is available at <https://www3.epa.gov/ttn/atw/rtr/rtrpg.html>.

A redline version of the regulatory language that incorporates the proposed changes in this action is available in the docket for this action (Docket ID No. EPA-HQ-OAR-2017-0015).

II. Background

A. What is the statutory authority for this action?

The statutory authority for this action is provided by sections 112 and 301 of the Clean Air Act (CAA), as amended (42 U.S.C. 7401 *et seq.*). Section 112 of the CAA establishes a two-stage regulatory process to develop standards for emissions of hazardous air pollutants (HAP) from stationary sources. Generally, the first stage involves establishing technology-based standards and the second stage involves evaluating those standards that are based on maximum achievable control technology (MACT) to determine whether additional standards are needed to address any remaining risk associated with HAP emissions. This second stage is commonly referred to as the “residual risk review.” In addition

to the residual risk review, the CAA also requires the EPA to review standards set under CAA section 112 every 8 years to determine if there are “developments in practices, processes, or control technologies” that may be appropriate to incorporate into the standards. This review is commonly referred to as the “technology review.” When the two reviews are combined into a single rulemaking, it is commonly referred to as the “risk and technology review.” The discussion that follows identifies the most relevant statutory sections and briefly explains the contours of the methodology used to implement these statutory requirements. A more comprehensive discussion appears in the document titled *CAA Section 112 Risk and Technology Reviews: Statutory Authority and Methodology*, in the docket for this rulemaking.

In the first stage of the CAA section 112 standard setting process, the EPA promulgates technology-based standards under CAA section 112(d) for categories of sources identified as emitting one or more of the HAP listed in CAA section 112(b). Sources of HAP emissions are either major sources or area sources, and CAA section 112 establishes different requirements for major source standards and area source standards. “Major sources” are those that emit or have the potential to emit 10 tons per year (tpy) or more of a single HAP or 25 tpy or more of any combination of HAP. All other sources are “area sources.” For major sources, CAA section 112(d)(2) provides that the technology-based NESHAP must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). These standards are commonly referred to as MACT

standards. CAA section 112(d)(3) also establishes a minimum control level for MACT standards, known as the MACT “floor.” The EPA must also consider control options that are more stringent than the floor. Standards more stringent than the floor are commonly referred to as beyond-the-floor standards. In certain instances, as provided in CAA section 112(h), the EPA may set work practice standards where it is not feasible to prescribe or enforce a numerical emission standard. For area sources, CAA section 112(d)(5) gives the EPA discretion to set standards based on generally available control technologies or management practices (GACT standards) in lieu of MACT standards.

The second stage in standard-setting focuses on identifying and addressing any remaining (*i.e.*, “residual”) risk according to CAA section 112(f). For source categories subject to MACT standards, section 112(f)(2) of the CAA requires the EPA to determine whether promulgation of additional standards is needed to provide an ample margin of safety to protect public health or to prevent an adverse environmental effect. Section 112(d)(5) of the CAA provides that this residual risk review is not required for categories of area sources subject to GACT standards. Section 112(f)(2)(B) of the CAA further expressly preserves the EPA’s use of the two-step approach for developing standards to address any residual risk and the Agency’s interpretation of “ample margin of safety” developed in the *National Emissions Standards for Hazardous Air Pollutants: Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants* (Benzene NESHAP) (54 FR 38044, September 14, 1989). The

EPA notified Congress in the Risk Report that the Agency intended to use the Benzene NESHAP approach in making CAA section 112(f) residual risk determinations (EPA-453/R-99-001, p. ES-11). The EPA subsequently adopted this approach in its residual risk determinations and the United States Court of Appeals for the District of Columbia Circuit (the Court) upheld the EPA's interpretation that CAA section 112(f)(2) incorporates the approach established in the Benzene NESHAP. See *NRDC v. EPA*, 529 F.3d 1077, 1083 (D.C. Cir. 2008).

The approach incorporated into the CAA and used by the EPA to evaluate residual risk and to develop standards under CAA section 112(f)(2) is a two-step approach. In the first step, the EPA determines whether risks are acceptable. This determination "considers all health information, including risk estimation uncertainty, and includes a presumptive limit on maximum individual lifetime [cancer] risk (MIR)¹ of approximately 1 in 10 thousand." 54 FR 38045, September 14, 1989. If risks are unacceptable, the EPA must determine the emissions standards necessary to reduce risk to an acceptable level without considering costs. In the second step of the approach, the EPA considers whether the emissions standards provide an ample margin of safety to protect public health "in consideration of all health information, including the number of persons at risk levels higher than approximately 1 in 1 million, as well as other relevant factors, including costs and economic impacts, technological feasibility, and other factors relevant to each particular decision." *Id.* The EPA must promulgate emission standards necessary to provide an ample margin of safety to protect public health or determine that the standards being reviewed provide an ample margin of safety without any revisions. After conducting the ample margin of safety analysis, we consider whether a more stringent standard is necessary to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.

CAA section 112(d)(6) separately requires the EPA to review standards promulgated under CAA section 112 and revise them "as necessary (taking into account developments in practices, processes, and control technologies)" no less often than every 8 years. In conducting this review, which we call

the "technology review," the EPA is not required to recalculate the MACT floor. *Natural Resources Defense Council (NRDC) v. EPA*, 529 F.3d 1077, 1084 (D.C. Cir. 2008). *Association of Battery Recyclers, Inc. v. EPA*, 716 F.3d 667 (D.C. Cir. 2013). The EPA may consider cost in deciding whether to revise the standards pursuant to CAA section 112(d)(6).

B. What is this source category and how does the current NESHAP regulate its HAP emissions?

The NESHAP for the Lime Manufacturing source category was promulgated on January 5, 2004 (69 FR 394), and codified at 40 CFR part 63, subpart AAAAA. As promulgated in 2004, the NESHAP regulates HAP emissions from all new and existing lime manufacturing plants that are major sources, co-located with major sources, or are part of major sources. However, lime manufacturing plants located at pulp and paper mills or at beet sugar factories are not subject to the NESHAP. Other captive lime manufacturing plants, such as (but not limited to) those at steel mills and magnesia production facilities, are subject to the NESHAP. See 67 FR 78053 explaining the basis for these determinations. A lime manufacturing plant is defined as any plant which uses a lime kiln to produce lime product from limestone or other calcareous material by calcination. However, the NESHAP specifically excludes lime kilns that use only calcium carbonate waste sludge from water softening processes as the feedstock. Lime product means the product of the lime kiln calcination process including calcitic lime, dolomitic lime, and dead-burned dolomite.

The NESHAP defines the affected source as follows: Each lime kiln and its associated cooler and each individual processed stone handling (PSH) operations system. The PSH operations system includes all equipment associated with PSH operations beginning at the process stone storage bin(s) or open storage pile(s) and ending where the process stone is fed into the kiln. It includes man-made process stone storage bins (but not open process stone storage piles), conveying system transfer points, bulk loading or unloading systems, screening operations, surge bins, bucket elevators, and belt conveyors. The materials processing operations associated with lime products (such as quicklime and hydrated lime), lime kiln dust handling, quarry or mining operations, limestone sizing operations, and fuels are not subject to the NESHAP. Processed stone

handling operations are further distinguished in the NESHAP as: (1) Whether their emissions are vented through a stack, (2) whether their emissions are fugitive emissions, (3) whether their emissions are vented through a stack with some fugitive emissions from the partial enclosure, and/or (4) whether the source is enclosed in a building. Finally, lime hydrators and cooler nuisance dust collectors are not included under the definition of affected source under the NESHAP.

The NESHAP established particulate matter (PM) emission limits for lime kilns, coolers, and PSH operations with stacks. Particulate matter is measured solely as a surrogate for the non-volatile and semi-volatile metal HAP. The NESHAP also regulates opacity or visible emissions from most of the PSH operations, with opacity also serving as a surrogate for non-volatile and semi-volatile HAP metals.

The PM emission limit for the existing kilns and coolers is 0.12 pounds PM per ton of stone feed (lb PM/tsf) for kilns using dry air pollution control systems prior to January 5, 2004. Existing kilns that have installed and are operating wet scrubbers prior to January 5, 2004, must meet an emission limit of 0.60 lb PM/tsf. Kilns which meet the criteria for the 0.60 lb PM/tsf emission limit must continue to use a wet scrubber for PM emission control in order to be eligible to meet the 0.60 lb PM/tsf limit. If at any time such a kiln switches to a dry control, they would become subject to the 0.12 lb PM/tsf emission limit, regardless of the type of control device used in the future. The PM emission limit for all new kilns and lime coolers is 0.10 lb PM/tsf. As a compliance option, these emission limits (except for the 0.60 lb PM/tsf limit) may be applied to the combined emissions of all the kilns and coolers at the lime manufacturing plant. If the lime manufacturing plant has both new and existing kilns and coolers, then the emission limit would be an average of the existing and new kiln PM emissions limits, weighted by the annual actual production rates of the individual kilns, except that no new kiln may exceed the PM emission level of 0.10 lb PM/tsf. Kilns that are required to meet a 0.60 lb PM/tsf emission limit must meet that limit individually, and may not be included in any averaging calculations. Emissions from PSH operations that are vented through a stack are subject to a limit of 0.05 grams PM per dry standard cubic meter (g PM/dscm) and 7-percent opacity. Stack emissions from PSH operations that are controlled by wet scrubbers are subject to the 0.05 g PM/

¹ Although defined as "maximum individual risk," MIR refers only to cancer risk. MIR, one metric for assessing cancer risk, is the estimated risk if an individual were exposed to the maximum level of a pollutant for a lifetime.

dscm limit but not subject to the opacity limit. Fugitive emissions from PSH operations are subject to a 10-percent opacity limit.

For each building enclosing any PSH operation, each of the affected PSH operations in the building must comply individually with the applicable PM and opacity emission limitations. Otherwise, there must be no visible emissions from the building, except from a vent, and the building's vent emissions must not exceed 0.05 g/dscm and 7-percent opacity. For each fabric filter that controls emissions from only an individual, enclosed processed stone storage bin, the opacity must not exceed 7 percent. For each set of multiple processed stone storage bins with combined stack emissions, emissions must not exceed 0.05 g/dscm and 7-percent opacity. The final rule does not allow averaging of PSH operations.

C. What data collection activities were conducted to support this action?

During the development of 40 CFR part 63, subpart AAAAA, the EPA collected information on the emissions, operations, and location of lime manufacturing plants. Since this information was collected prior to the 2004 promulgation of 40 CFR part 63, subpart AAAAA, the EPA prepared a questionnaire in 2017 in order to collect current information on the location and number of lime kilns, types and quantities of emissions, annual operating hours, types and quantities of fuels burned, and information on air pollution control devices and emission points. Nine companies completed the 2017 questionnaire for which they reported data for 32 of 35 major source facilities. The EPA used data from the 2017 questionnaires to develop the dataset for the NESHP risk assessment.

The list of facilities that are subject to the NESHP was developed using the EPA's Enforcement and Compliance History Online (ECHO) database, the 2014 National Emission Inventory (NEI 2014) and the U.S. Geological Survey's (USGS's) Directory of Lime Plants and Hydration Plants in the United States in 2014. The list of facilities, as well as which companies would receive the questionnaire, was reviewed by the industry trade association. The final risk modeling datafile included all 35 major source facilities.

D. What other relevant background information and data are available?

In addition to the ECHO and NEI databases, the EPA reviewed the additional information sources listed below and consulted with stakeholders regulated under the Lime Manufacturing

NESHAP to determine whether there have been developments in practices, processes, or control technologies by lime manufacturing sources. These include the following:

- Permit limits and selected compliance options from permits submitted by facilities as part of their response to the questionnaire and collected from state agencies;
- Information on air pollution control options in the lime manufacturing industry from the Reasonably Available Control Technology/Best Available Control Technology/Lowest Achievable Emission Rate Clearinghouse (RBLC); and
- Communication with trade groups and associations representing industries in the affected NAICS categories and their members.

III. Analytical Procedures and Decision-Making

In this section, we describe the analyses performed to support the proposed decisions for the RTR and other issues addressed in this action.

A. How do we consider risk in our decision-making?

As discussed in section II.A of this preamble and in the Benzene NESHP, in evaluating and developing standards under CAA section 112(f)(2), we apply a two-step approach to determine whether or not risks are acceptable and to determine if the standards provide an ample margin of safety to protect public health. As explained in the Benzene NESHP, “the first step judgment on acceptability cannot be reduced to any single factor” and, thus, “[t]he Administrator believes that the acceptability of risk under section 112 is best judged on the basis of a broad set of health risk measures and information.” 54 FR 38046, September 14, 1989. Similarly, with regard to the ample margin of safety determination, “the Agency again considers all of the health risk and other health information considered in the first step. Beyond that information, additional factors relating to the appropriate level of control will also be considered, including cost and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors.” *Id.*

The Benzene NESHP approach provides flexibility regarding factors the EPA may consider in making determinations and how the EPA may weigh those factors for each source category. The EPA conducts a risk assessment that provides estimates of the MIR posed by the HAP emissions from each source in the source category, the hazard index (HI) for chronic

exposures to HAP with the potential to cause noncancer health effects, and the hazard quotient (HQ) for acute exposures to HAP with the potential to cause noncancer health effects.² The assessment also provides estimates of the distribution of cancer risk within the exposed populations, cancer incidence, and an evaluation of the potential for an adverse environmental effect. The scope of the EPA's risk analysis is consistent with the EPA's response to comments on our policy under the Benzene NESHP where the EPA explained that:

[t]he policy chosen by the Administrator permits consideration of multiple measures of health risk. Not only can the MIR figure be considered, but also incidence, the presence of non-cancer health effects, and the uncertainties of the risk estimates. In this way, the effect on the most exposed individuals can be reviewed as well as the impact on the general public. These factors can then be weighed in each individual case. This approach complies with the *Vinyl Chloride* mandate that the Administrator ascertain an acceptable level of risk to the public by employing his expertise to assess available data. It also complies with the Congressional intent behind the CAA, which did not exclude the use of any particular measure of public health risk from the EPA's consideration with respect to CAA section 112 regulations, and thereby implicitly permits consideration of any and all measures of health risk which the Administrator, in his judgment, believes are appropriate to determining what will ‘protect the public health’.

See 54 FR 38057, September 14, 1989. Thus, the level of the MIR is only one factor to be weighed in determining acceptability of risk. The Benzene NESHP explained that “an MIR of approximately one in 10 thousand should ordinarily be the upper end of the range of acceptability. As risks increase above this benchmark, they become presumptively less acceptable under CAA section 112, and would be weighed with the other health risk measures and information in making an overall judgment on acceptability. Or, the Agency may find, in a particular case, that a risk that includes an MIR less than the presumptively acceptable level is unacceptable in the light of other health risk factors.” *Id.* at 38045. In other words, risks that include an MIR above 100-in-1 million may be determined to be acceptable, and risks with an MIR below that level may be determined to be unacceptable, depending on all of the available health

² The MIR is defined as the cancer risk associated with a lifetime of exposure at the highest concentration of HAP where people are likely to live. The HQ is the ratio of the potential HAP exposure concentration to the noncancer dose-response value; the HI is the sum of HQs for HAP that affect the same target organ or organ system.

information. Similarly, with regard to the ample margin of safety analysis, the EPA stated in the Benzene NESHAP that: “EPA believes the relative weight of the many factors that can be considered in selecting an ample margin of safety can only be determined for each specific source category. This occurs mainly because technological and economic factors (along with the health-related factors) vary from source category to source category.” *Id.* at 38061. We also consider the uncertainties associated with the various risk analyses, as discussed earlier in this preamble, in our determinations of acceptability and ample margin of safety.

The EPA notes that it has not considered certain health information to date in making residual risk determinations. At this time, we do not attempt to quantify the HAP risk that may be associated with emissions from other facilities that do not include the source category under review, mobile source emissions, natural source emissions, persistent environmental pollution, or atmospheric transformation in the vicinity of the sources in the category.

The EPA understands the potential importance of considering an individual’s total exposure to HAP in addition to considering exposure to HAP emissions from the source category and facility. We recognize that such consideration may be particularly important when assessing noncancer risk, where pollutant-specific exposure health reference levels (*e.g.*, reference concentrations (RfCs)) are based on the assumption that thresholds exist for adverse health effects. For example, the EPA recognizes that, although exposures attributable to emissions from a source category or facility alone may not indicate the potential for increased risk of adverse noncancer health effects in a population, the exposures resulting from emissions from the facility in combination with emissions from all of the other sources (*e.g.*, other facilities) to which an individual is exposed may be sufficient to result in an increased risk of adverse noncancer health effects. In May 2010, the Science Advisory Board (SAB) advised the EPA “that RTR assessments will be most useful to decision makers and communities if results are presented in the broader context of aggregate and cumulative risks, including background concentrations and contributions from other sources in the area.”³

In response to the SAB recommendations, the EPA incorporates cumulative risk analyses into its RTR risk assessments, including those reflected in this action. The Agency (1) conducts facility-wide assessments, which include source category emission points, as well as other emission points within the facilities; (2) combines exposures from multiple sources in the same category that could affect the same individuals; and (3) for some persistent and bioaccumulative pollutants, analyzes the ingestion route of exposure. In addition, the RTR risk assessments consider aggregate cancer risk from all carcinogens and aggregated noncancer HQs for all noncarcinogens affecting the same target organ or target organ system.

Although we are interested in placing source category and facility-wide HAP risk in the context of total HAP risk from all sources combined in the vicinity of each source, we are concerned about the uncertainties of doing so. Estimates of total HAP risk from emission sources other than those that we have studied in depth during this RTR review would have significantly greater associated uncertainties than the source category or facility-wide estimates. Such aggregate or cumulative assessments would compound those uncertainties, making the assessments too unreliable.

B. How do we perform the technology review?

Our technology review focuses on the identification and evaluation of developments in practices, processes, and control technologies that have occurred since the MACT standards were promulgated. Where we identify such developments, we analyze their technical feasibility, estimated costs, energy implications, and non-air environmental impacts. We also consider the emission reductions associated with applying each development. This analysis informs our decision of whether it is “necessary” to revise the emissions standards. In addition, we consider the appropriateness of applying controls to new sources versus retrofitting existing sources. For this exercise, we consider any of the following to be a “development”:

- Any add-on control technology or other equipment that was not identified and considered during development of the original MACT standards;

- Any improvements in add-on control technology or other equipment (that were identified and considered during development of the original MACT standards) that could result in additional emissions reduction;

- Any work practice or operational procedure that was not identified or considered during development of the original MACT standards;

- Any process change or pollution prevention alternative that could be broadly applied to the industry and that was not identified or considered during development of the original MACT standards; and

- Any significant changes in the cost (including cost effectiveness) of applying controls (including controls the EPA considered during the development of the original MACT standards).

In addition to reviewing the practices, processes, and control technologies that were considered at the time we originally developed the NESHAP, we review a variety of data sources in our investigation of potential practices, processes, or controls to consider. See sections II.C and II.D of this preamble for information on the specific data sources that were reviewed as part of the technology review.

C. How do we estimate post-MACT risk posed by the source category?

In this section, we provide a complete description of the types of analyses that we generally perform during the risk assessment process. In some cases, we do not perform a specific analysis because it is not relevant. For example, in the absence of emissions of HAP known to be persistent and bioaccumulative in the environment (PB-HAP), we would not perform a multipathway exposure assessment. Where we do not perform an analysis, we state that we do not and provide the reason. While we present all of our risk assessment methods, we only present risk assessment results for the analyses actually conducted (see section IV.B of this preamble).

The EPA conducts a risk assessment that provides estimates of the MIR for cancer posed by the HAP emissions from each source in the source category, the HI for chronic exposures to HAP with the potential to cause noncancer health effects, and the HQ for acute exposures to HAP with the potential to cause noncancer health effects. The assessment also provides estimates of the distribution of cancer risk within the exposed populations, cancer incidence, and an evaluation of the potential for an adverse environmental effect. The seven sections that follow this paragraph

³ Recommendations of the SAB Risk and Technology Review Methods Panel are provided in their report, which is available at: [https://yosemite.epa.gov/sab/sabproduct.nsf/4AB3966E263D943A8525771F00668381/\\$File/EPA-SAB-10-007-unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/4AB3966E263D943A8525771F00668381/$File/EPA-SAB-10-007-unsigned.pdf).

describe how we estimated emissions and conducted the risk assessment. The docket for this rulemaking contains the following document which provides more information on the risk assessment inputs and models: *Residual Risk Assessment for the Lime Manufacturing Source Category in Support of the 2019 Risk and Technology Review Proposed Rule*. The methods used to assess risk (as described in the seven primary steps below) are consistent with those described by the EPA in the document reviewed by a panel of the EPA's SAB in 2009;⁴ and described in the SAB review report issued in 2010. They are also consistent with the key recommendations contained in that report.

1. How did we estimate actual emissions and identify the emissions release characteristics?

A questionnaire was sent out to nine companies (covering 44 facilities) in 2017. The available test data collected were from the 1990's through 2017. Of the 44 facilities that received the questionnaire, 32 were verified to be major sources and were included in the modeling file. Based on the results of the questionnaire and research into three non-questionnaire facilities, there are 96 lime kilns at the 35 major sources subject to the Lime Manufacturing Plants NESHA.

Particulate matter test data were provided for most of the lime kilns and the lime kiln and coolers with common exhausts. PM particle size by the kiln emission control type was assigned based on data from AP-42.⁵ For kiln controls or other sources not listed in AP-42, default particles sizes and mass distributions were used for the entire source category. In addition to kiln data, a small amount of PSH operations provided emissions test data in response to the questionnaire. Because there was so little test data for PSH operations, air emissions inventory (AEI) data⁶ were

used as the source of PSH PM emissions in lieu of the limited test data.

Test data for HAP metals were provided for 17 emission release points of lime kilns. Data were provided both for kilns only, and for kilns with co-mingled lime cooler exhaust. Because the data set received was very limited and the emissions were not significantly different, emissions data from stand-alone kilns and shared stacks were treated as similar rather than categorized separately for purposes of estimating emissions. For non-mercury HAP metals, test data were used in conjunction with corresponding PM data to develop mass fractions of HAP metals (*i.e.*, HAP metal/PM). These were applied to PM test data to estimate HAP metal emissions for kilns, coolers, and kilns/coolers with common exhaust. For mercury emissions, test results were used in conjunction with operating hours to estimate annual mercury emissions for kilns, coolers, and kilns/coolers with common exhaust.

Test data for hydrochloric acid (HCl) were provided for 33 emission release points of lime kilns and kilns/coolers with common exhausts. Organic HAP test data were provided for nine emission release points of kilns/coolers with common exhaust. Dioxins and furans (D/F) test data were provided for five emission release points of both lime kilns and kilns/coolers with common exhausts.

Because the HAP emissions data set received is very limited, emission factors were developed from test data collected from the questionnaire and AEI data. When emissions test data or AEI data were available for an applicable emission unit, the average emission rate of the available data was applied to that applicable emissions unit. In cases where data were unavailable for an applicable emission unit, default emissions values were developed and assigned as needed. Emission defaults were determined as the average of all test or AEI data in each applicable emission unit category (*e.g.*, kiln vs. PSH operations) or sub-category (*e.g.*, existing kilns with wet scrubbers).

Due to the nature of the data provided for PM and HAP compounds (*i.e.*, HAP metal, HCl, organic HAP, and D/F), stand-alone kilns and kilns/coolers with common exhausts were treated the same rather than categorizing their emissions separately. Specifically, there were not enough data (*e.g.*, in the case of HAP metals, organic HAP, and D/F) provided for stand-alone kilns and kiln/coolers with common exhausts or variation (*e.g.*, in the case of PM and HCl) in the data to justify the development of sub-categorized emission factor sets based

on the difference between stand-alone kilns and kilns that had co-mingled kiln and cooler stacks. PSH operations did not require review or development of individual sub-categories.

For units that did not provide test result data, default emission rates were developed based on the category of kiln/cooler (new or existing) and the service date of the wet scrubber (before or after January 5, 2004), since these factors align with the PM emission limits of the kiln in the rule. To develop default factors for PM and HCl, the average test results of all single kiln emission units by category/status were determined for each of three default categories: Existing kilns with a wet scrubber installed before January 5, 2004, existing kilns without a wet scrubber installed before January 5, 2004, and new kilns.

Six stand-alone lime coolers were reported through the questionnaire. Of these, four reported PM emissions test data for a total of eleven PM test reports. For these four coolers, emissions were determined as the average of the reported PM test data for each applicable emission unit. The two remaining lime coolers were assigned a default value that was developed as the average of the emissions from the four coolers.

All of the PSH operations were reported as fugitive sources in the questionnaire, with the exception of eleven point source PSH emission units. Very little PM emissions test data were provided for PSH operations, so emissions from these sources were determined from reported 2015 and 2016 AEIs, where available. Emissions values were tallied in units of tpy. Most questionnaire respondents provided AEIs in their responses. However, not all AEIs have PSH emissions reported explicitly, and for those that did, some of the unit names/IDs did not match with those reported in the questionnaire. The questionnaire emission release point IDs were used as the basis for developing PM emissions from AEI data. Emissions data per unit was assigned using AEIs where the unit names matched, averaging the 2015 and 2016 values. Units with no AEI data were assigned the default PM emissions average that was developed from AEI data.

To determine the actual annual emissions of non-mercury HAP metals in tpy from kilns and kiln/coolers with common exhausts, PM emissions were first determined using available test data. Each kiln emissions unit was assigned a PM value based on average actual EPA Method 5 test data for the unit or assigned a default value if PM test data were unavailable. PM

⁴ U.S. EPA. *Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies—MACT I Petroleum Refining Sources and Portland Cement Manufacturing*, June 2009. EPA-452/R-09-006. <https://www3.epa.gov/airtoxics/rtrisk/rtrpg.html>.

⁵ *Compilation of Air Pollutant Emissions Factors, AP-42, Fifth Edition, Volume 1: Stationary Point and Area Sources*, U.S. Environmental Protection Agency, Research Triangle Park, NC, January 1995.

⁶ Title V of the Clean Air Act requires major sources of air pollution and certain other facilities to apply for and obtain title V operating permits. State and local authorities overseeing the title V permitting program typically require permit holders to develop annual air emissions inventories for the purposes of fee determination. These annual inventories were requested in the questionnaire and the data were used for this modeling effort.

emissions in units of pounds per hour (lb/hr) were determined as the average of reported test values (or developed default value) times the rate of stone feed during the most recent performance test (collected through questionnaire) in units of tons of stone feed per hour. When the rate of stone feed per hour was unreported or claimed as CBI, a default rate (determined as the average of all reported rates) was assigned. Annual PM emissions in units of tpy were determined by multiplying hourly PM emissions by the actual annual emission unit operating hours reported in the Information Collection Request (ICR) and also by the unit conversion from pounds to tons. When the emission unit operating hours were unreported or claimed as CBI, a default value (determined as the average of all reported operating hours) was assigned. Actual annual PM emissions were then speciated per the HAP metal emission factor sets.

Actual emissions of mercury, HCl, organic HAP, and D/F emissions for kilns and kiln/coolers with common exhausts were based on the test data reported to the questionnaire (in units of lb/hr) multiplied by the reported actual operating hours of each unit. When the emission unit operating hours were unreported or claimed as CBI, a default value (determined as the average of all reported operating hours) was assigned.

Stand-alone lime coolers only emit PM and metal HAP constituents. Most of the lime coolers reported through the questionnaire were annotated as being co-mingled with kiln exhaust, not stand-alone emission units. However, six stand-alone lime coolers were reported to the questionnaire. There were no metal HAP test data provided for stand-alone lime coolers through the questionnaire. As such, one universal set of default metal HAP mass fractions of PM was developed from kiln test data. These defaults were applied to all other PM emission units, including stand-alone coolers. When the rate of stone feed or operating hours were unreported or claimed as CBI, default rates (determined as the average of all reported rates) were assigned.

Process stone handling operations have the potential to emit HAP metals in limestone dust. Eleven PSH units were identified as venting emissions through a stack and the remaining PSH data were modeled as fugitive emissions due to a lack of data in the questionnaire. Operating hours were not specifically reported for PSH operations, so average kiln operating hours were used when reported, otherwise kiln default operating hours were used. Actual emissions were determined

using the reported or default PM emissions developed from the AEI multiplied by the HAP speciation.

2. How did we estimate MACT-allowable emissions?

The available emissions data in the RTR emissions dataset include estimates of the mass of HAP emitted during a specified annual time period. These “actual” emission levels are often lower than the emission levels allowed under the requirements of the current MACT standards. The emissions allowed under the MACT standards are referred to as the “MACT-allowable” emissions. We discussed the consideration of both MACT-allowable and actual emissions in the final Coke Oven Batteries RTR (70 FR 19998–19999, April 15, 2005) and in the proposed and final Hazardous Organic NESHAP RTR (71 FR 34428, June 14, 2006, and 71 FR 76609, December 21, 2006, respectively). In those actions, we noted that assessing the risk at the MACT-allowable level is inherently reasonable since that risk reflects the maximum level facilities could emit and still comply with national emission standards. We also explained that it is reasonable to consider actual emissions, where such data are available, in both steps of the risk analysis, in accordance with the Benzene NESHAP approach. (54 FR 38044, September 14, 1989.)

Allowable HAP metal emissions were calculated by using the existing applicable PM limit, scaled production, and the maximum operating hours per year of 8,760. The hourly production scalar (*i.e.*, tsf scalar) was developed by comparing the rate of production during the most recent performance test (which is used for the actual emission calculation) to the maximum production capacity. Site specific scalars and one default scalar were developed to scale the test production rate to the maximum capacity. Where production data were unreported or claimed as CBI, default rates were developed. For more details on the development of the default values, see the memorandum titled *Development of the RTR Emissions Dataset for the Lime Manufacturing Source Category*, in the docket for this rulemaking (Docket ID No. EPA–HQ–OAR–2017–0015).

Allowable emissions of mercury, HCl, organic HAP, and D/F emissions for kilns and kiln/coolers with common exhausts were calculated using 8,760 hours. Allowable emissions for PSH operations were determined in the same manner as described above for actual emissions, except that emissions were scaled up according to the ratio of total

operating hours over actual operating hours.

3. How do we conduct dispersion modeling, determine inhalation exposures, and estimate individual and population inhalation risk?

Both long-term and short-term inhalation exposure concentrations and health risk from the source category addressed in this action were estimated using the Human Exposure Model (HEM–3).⁷ The HEM–3 performs three primary risk assessment activities: (1) Conducting dispersion modeling to estimate the concentrations of HAP in ambient air, (2) estimating long-term and short-term inhalation exposures to individuals residing within 50 kilometers (km) of the modeled sources, and (3) estimating individual and population-level inhalation risk using the exposure estimates and quantitative dose-response information.

a. Dispersion Modeling

The air dispersion model AERMOD, used by the HEM–3 model, is one of the EPA’s preferred models for assessing air pollutant concentrations from industrial facilities.⁸ To perform the dispersion modeling and to develop the preliminary risk estimates, HEM–3 draws on three data libraries. The first is a library of meteorological data, which is used for dispersion calculations. This library includes 1 year (2016) of hourly surface and upper air observations from 824 meteorological stations, selected to provide coverage of the United States and Puerto Rico. A second library of United States Census Bureau census block⁹ internal point locations and populations provides the basis of human exposure calculations (U.S. Census, 2010). In addition, for each census block, the census library includes the elevation and controlling hill height, which are also used in dispersion calculations. A third library of pollutant-specific dose-response values is used to estimate health risk. These are discussed below.

b. Risk From Chronic Exposure to HAP

In developing the risk assessment for chronic exposures, we use the estimated annual average ambient air concentrations of each HAP emitted by

⁷ For more information about HEM–3, go to <https://www.epa.gov/fera/risk-assessment-and-modeling-human-exposure-model-hem>.

⁸ U.S. EPA. Revision to the *Guideline on Air Quality Models: Adoption of a Preferred General Purpose (Flat and Complex Terrain) Dispersion Model and Other Revisions* (70 FR 68218, November 9, 2005).

⁹ A census block is the smallest geographic area for which census statistics are tabulated.

each source in the source category. The HAP air concentrations at each nearby census block centroid located within 50 km of the facility are a surrogate for the chronic inhalation exposure concentration for all the people who reside in that census block. A distance of 50 km is consistent with both the analysis supporting the 1989 Benzene NESHAP (54 FR 38044, September 14, 1989) and the limitations of Gaussian dispersion models, including AERMOD.

For each facility, we calculate the MIR as the cancer risk associated with a continuous lifetime (24 hours per day, 7 days per week, 52 weeks per year, 70 years) exposure to the maximum concentration at the centroid of each inhabited census block. We calculate individual cancer risk by multiplying the estimated lifetime exposure to the ambient concentration of each HAP (in micrograms per cubic meter ($\mu\text{g}/\text{m}^3$)) by its unit risk estimate (URE). The URE is an upper-bound estimate of an individual's incremental risk of contracting cancer over a lifetime of exposure to a concentration of 1 microgram of the pollutant per cubic meter of air. For residual risk assessments, we generally use UREs from the EPA's Integrated Risk Information System (IRIS). For carcinogenic pollutants without IRIS values, we look to other reputable sources of cancer dose-response values, often using California EPA (CalEPA) UREs, where available. In cases where new, scientifically credible dose-response values have been developed in a manner consistent with EPA guidelines and have undergone a peer review process similar to that used by the EPA, we may use such dose-response values in place of, or in addition to, other values, if appropriate. The pollutant-specific dose-response values used to estimate health risk are available at <https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants>.

To estimate individual lifetime cancer risks associated with exposure to HAP emissions from each facility in the source category, we sum the risks for each of the carcinogenic HAP¹⁰ emitted

by the modeled facility. We estimate cancer risk at every census block within 50 km of every facility in the source category. The MIR is the highest individual lifetime cancer risk estimated for any of those census blocks. In addition to calculating the MIR, we estimate the distribution of individual cancer risks for the source category by summing the number of individuals within 50 km of the sources whose estimated risk falls within a specified risk range. We also estimate annual cancer incidence by multiplying the estimated lifetime cancer risk at each census block by the number of people residing in that block, summing results for all of the census blocks, and then dividing this result by a 70-year lifetime.

To assess the risk of noncancer health effects from chronic exposure to HAP, we calculate either an HQ or a target organ-specific hazard index (TOSHI). We calculate an HQ when a single noncancer HAP is emitted. Where more than one noncancer HAP is emitted, we sum the HQ for each of the HAP that affects a common target organ or target organ system to obtain a TOSHI. The HQ is the estimated exposure divided by the chronic noncancer dose-response value, which is a value selected from one of several sources. The preferred chronic noncancer dose-response value is the EPA RfC, defined as "an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime" (https://iaspub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&vocabName=IRIS%20Glossary). In cases where an RfC from the EPA's IRIS is not available or where the EPA determines that using a value other than the RfC is appropriate, the chronic noncancer dose-response value can be a value from the following prioritized sources, which define their dose-response values similarly to the EPA: (1) The Agency for Toxic Substances and Disease Registry (ATSDR) Minimum

Risk Level (<https://www.atsdr.cdc.gov/mrls/index.asp>); (2) the CalEPA Chronic Reference Exposure Level (REL) (<https://oehha.ca.gov/air/crnrr/notice-adoption-air-toxics-hot-spots-program-guidance-manual-preparation-health-risk-0>); or (3), as noted above, a scientifically credible dose-response value that has been developed in a manner consistent with the EPA guidelines and has undergone a peer review process similar to that used by the EPA. The pollutant-specific dose-response values used to estimate health risks are available at <https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants>.

c. Risk From Acute Exposure to HAP That May Cause Health Effects Other Than Cancer

For each HAP for which appropriate acute inhalation dose-response values are available, the EPA also assesses the potential health risks due to acute exposure. For these assessments, the EPA makes conservative assumptions about emission rates, meteorology, and exposure location. In this proposed rulemaking, as part of our efforts to continually improve our methodologies to evaluate the risks that HAP emitted from categories of industrial sources pose to human health and the environment,¹¹ we are revising our treatment of meteorological data to use reasonable worst-case air dispersion conditions in our acute risk screening assessments instead of worst-case air dispersion conditions. This revised treatment of meteorological data and the supporting rationale are described in more detail in *Residual Risk Assessment for Lime Manufacturing Source Category in Support of the 2019 Risk and Technology Review Proposed Rule* and in Appendix 5 of the report: *Technical Support Document for Acute Risk Screening Assessment*. We will be applying this revision in RTR rulemakings proposed on or after June 3, 2019.

To assess the potential acute risk to the maximally exposed individual, we use the peak hourly emission rate for each emission point,¹² reasonable

¹⁰ The EPA's 2005 *Guidelines for Carcinogen Risk Assessment* classifies carcinogens as: "carcinogenic to humans," "likely to be carcinogenic to humans," and "suggestive evidence of carcinogenic potential." These classifications also coincide with the terms "known carcinogen, probable carcinogen, and possible carcinogen," respectively, which are the terms advocated in the EPA's *Guidelines for Carcinogen Risk Assessment*, published in 1986 (51 FR 33992, September 24, 1986). In August 2000, the document, *Supplemental Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (EPA/630/R-00/002), was published as a

supplement to the 1986 document. Copies of both documents can be obtained from <https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=20533&CFID=70315376&CFTOKEN=71597944>. Summing the risk of these individual compounds to obtain the cumulative cancer risk is an approach that was recommended by the EPA's SAB in their 2002 peer review of the EPA's National Air Toxics Assessment (NATA) titled *NATA—Evaluating the National-scale Air Toxics Assessment 1996 Data—an SAB Advisory*, available at [https://yosemite.epa.gov/sab/sabproduct.nsf/214C6E915B04E14852570CA007A682C/\\$File/ecadv02001.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/214C6E915B04E14852570CA007A682C/$File/ecadv02001.pdf).

¹¹ See, e.g., U.S. EPA. *Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis* (Draft Report, May 2017. <https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html>).

¹² In the absence of hourly emission data, we develop estimates of maximum hourly emission rates by multiplying the average actual annual emissions rates by a factor (either a category-specific factor or a default factor of 10) to account for variability. This is documented in *Residual Risk Assessment for Lime Manufacturing Source Category in Support of the 2019 Risk and Technology Review Proposed Rule* and in Appendix

worst-case air dispersion conditions (i.e., 99th percentile), and the point of highest off-site exposure. Specifically, we assume that peak emissions from the source category and reasonable worst-case air dispersion conditions co-occur and that a person is present at the point of maximum exposure.

To characterize the potential health risks associated with estimated acute inhalation exposures to a HAP, we generally use multiple acute dose-response values, including acute RELs, acute exposure guideline levels (AEGLs), and emergency response planning guidelines (ERPG) for 1-hour exposure durations, if available, to calculate acute HQs. The acute HQ is calculated by dividing the estimated acute exposure concentration by the acute dose-response value. For each HAP for which acute dose-response values are available, the EPA calculates acute HQs.

An acute REL is defined as “the concentration level at or below which no adverse health effects are anticipated for a specified exposure duration.”¹³ Acute RELs are based on the most sensitive, relevant, adverse health effect reported in the peer-reviewed medical and toxicological literature. They are designed to protect the most sensitive individuals in the population through the inclusion of margins of safety. Because margins of safety are incorporated to address data gaps and uncertainties, exceeding the REL does not automatically indicate an adverse health impact. AEGLs represent threshold exposure limits for the general public and are applicable to emergency exposures ranging from 10 minutes to 8 hours.¹⁴ They are guideline levels for “once-in-a-lifetime, short-term exposures to airborne concentrations of acutely toxic, high-priority chemicals.” *Id.* at 21. The AEGL-1 is specifically

defined as “the airborne concentration (expressed as ppm (parts per million) or mg/m³ (milligrams per cubic meter)) of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.” The document also notes that “Airborne concentrations below AEGL-1 represent exposure levels that can produce mild and progressively increasing but transient and nondisabling odor, taste, and sensory irritation or certain asymptomatic, nonsensory effects.” *Id.* AEGL-2 are defined as “the airborne concentration (expressed as parts per million or milligrams per cubic meter) of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.” *Id.*

ERPGs are “developed for emergency planning and are intended as health-based guideline concentrations for single exposures to chemicals.”¹⁵ *Id.* at 1. The ERPG-1 is defined as “the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing other than mild transient adverse health effects or without perceiving a clearly defined, objectionable odor.” *Id.* at 2. Similarly, the ERPG-2 is defined as “the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to one hour without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual’s ability to take protective action.” *Id.* at 1.

An acute REL for 1-hour exposure durations is typically lower than its corresponding AEGL-1 and ERPG-1. Even though their definitions are slightly different, AEGL-1s are often the same as the corresponding ERPG-1s, and AEGL-2s are often equal to ERPG-2s. The maximum HQs from our acute inhalation screening risk assessment typically result when we use the acute REL for a HAP. In cases where the maximum acute HQ exceeds 1, we also

report the HQ based on the next highest acute dose-response value (usually the AEGL-1 and/or the ERPG-1).

For this source category, we used the default acute multiplier of 10 to derive a conservative estimate of maximum hourly emissions from annual emissions. In our acute inhalation screening risk assessment, acute impacts are deemed negligible for HAP for which acute HQs are less than or equal to 1, and no further analysis is performed for these HAP. In cases where an acute HQ from the screening step is greater than 1, we assess the site-specific data to ensure we have assessed the acute HQ at an off-site location. For this source category, we did not have to perform any refined acute assessments.

4. How do we conduct the multipathway exposure and risk screening assessment?

The EPA conducts a tiered screening assessment examining the potential for significant human health risks due to exposures via routes other than inhalation (i.e., ingestion). We first determine whether any sources in the source category emit any HAP known to be persistent and bioaccumulative in the environment, as identified in the EPA’s Air Toxics Risk Assessment Library (see Volume 1, Appendix D, at <https://www.epa.gov/fera/risk-assessment-and-modeling-air-toxics-risk-assessment-reference-library>).

For the Lime Manufacturing source category, we identified PB-HAP emissions of arsenic, D/F, cadmium, mercury, and lead, so we proceeded to the next step of the evaluation. Except for lead, the human health risk screening assessment for PB-HAP consists of three progressive tiers. In a Tier 1 screening assessment, we determine whether the magnitude of the facility-specific emissions of PB-HAP warrants further evaluation to characterize human health risk through ingestion exposure. To facilitate this step, we evaluate emissions against previously developed screening threshold emission rates for several PB-HAP that are based on a hypothetical upper-end screening exposure scenario developed for use in conjunction with the EPA’s Total Risk Integrated Methodology. Fate, Transport, and Ecological Exposure (TRIM.FaTE) model. The PB-HAP with screening threshold emission rates are arsenic compounds, cadmium compounds, chlorinated dibenzodioxins and furans, mercury compounds, and polycyclic organic matter (POM). Based on the EPA estimates of toxicity and bioaccumulation potential, these pollutants represent a conservative list

5 of the report: *Technical Support Document for Acute Risk Screening Assessment*. Both are available in the docket for this rulemaking.

¹³ CalEPA issues acute RELs as part of its Air Toxics Hot Spots Program, and the 1-hour and 8-hour values are documented in *Air Toxics Hot Spots Program Risk Assessment Guidelines, Part I, The Determination of Acute Reference Exposure Levels for Airborne Toxicants*, which is available at <https://oehha.ca.gov/air/general-info/oehha-acute-8-hour-and-chronic-reference-exposure-level-rel-summary>.

¹⁴ National Academy of Sciences, 2001. *Standing Operating Procedures for Developing Acute Exposure Levels for Hazardous Chemicals*, page 2. Available at https://www.epa.gov/sites/production/files/2015-09/documents/sop_final_standing_operating_procedures_2001.pdf. Note that the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances ended in October 2011, but the AEGL program continues to operate at the EPA and works with the National Academies to publish final AEGLs (<https://www.epa.gov/aegl>).

¹⁵ ERPGS Procedures and Responsibilities. March 2014. American Industrial Hygiene Association. Available at: <https://www.aiha.org/get-involved/AIHA-Guideline-Foundation/Emergency-Response-Planning-Guidelines/Documents/ERPG%20Committee%20Standard%20Operating%20Procedures%20-%20March%202014%20Revision%20-%28Updated%2010-2-2014%29.pdf>.

for inclusion in multipathway risk assessments for RTR rules. (See Volume 1, Appendix D at https://www.epa.gov/sites/production/files/2013-08/documents/volume_1_reflibrary.pdf.) The ratio of a facility's actual emission rate to the Tier 1 screening threshold emission rate is a "screening value."

We derive the Tier 1 screening threshold emission rates for these PB-HAP (other than lead compounds) to correspond to a maximum excess lifetime cancer risk of 1-in-1 million (*i.e.*, for arsenic compounds, polychlorinated dibenzodioxins and furans, and POM) or, for HAP that cause noncancer health effects (*i.e.*, cadmium compounds and mercury compounds), a maximum HQ of 1. If the emission rate of any one PB-HAP or combination of carcinogenic PB-HAP in the Tier 1 screening assessment exceeds the Tier 1 screening threshold emission rate for any facility (*i.e.*, the screening value is greater than 1), we conduct a second screening assessment, which we call the Tier 2 screening assessment. The Tier 2 screening assessment separates the Tier 1 combined fisher and farmer exposure scenario into fisher, farmer, and gardener scenarios that retain upper-bound ingestion rates.

In the Tier 2 screening assessment, the location of each facility that exceeds a Tier 1 screening threshold emission rate is used to refine the assumptions associated with the Tier 1 fisher/farmer scenario. A key assumption in the Tier 1 screening assessment is that a lake and/or farm is located near the facility. As part of the Tier 2 screening assessment, we use a USGS database to identify actual waterbodies within 50 km of each facility and assume the fisher only consumes fish from lakes within that 50 km zone. We also examine the differences between local meteorology near the facility and the meteorology used in the Tier 1 screening assessment. We then adjust the previously-developed Tier 1 screening threshold emission rates for each PB-HAP for each facility based on an understanding of how exposure concentrations estimated for the screening scenario change with the use of local meteorology and the USGS lakes database.

In the Tier 2 farmer scenario, we maintain an assumption that the farm is located within 0.5 km of the facility and that the farmer consumes meat, eggs, dairy, vegetables, and fruit produced near the facility. We may further refine the Tier 2 screening analysis by assessing a gardener scenario to characterize a range of exposures, with the gardener scenario being more plausible in RTR evaluations. Under the

gardener scenario, we assume the gardener consumes home-produced eggs, vegetables, and fruit products at the same ingestion rate as the farmer. The Tier 2 screen continues to rely on the high-end food intake assumptions that were applied in Tier 1 for local fish (adult female angler at 99th percentile consumption of fish¹⁶) and locally grown or raised foods (90th percentile consumption of locally grown or raised foods for the farmer and gardener scenarios¹⁷). If PB-HAP emission rates do not result in a Tier 2 screening value greater than 1, we consider those PB-HAP emissions to pose risks below a level of concern. If the PB-HAP emission rates for a facility exceed the Tier 2 screening threshold emission rates, we may conduct a Tier 3 screening assessment.

There are several analyses that can be included in a Tier 3 screening assessment, depending upon the extent of refinement warranted, including validating that the impacted lakes are fishable, locating residential/garden locations for urban and/or rural settings, considering plume-rise to estimate emissions lost above the mixing layer, and considering hourly effects of meteorology and plume rise on chemical fate and transport (a time-series analysis). If necessary, the EPA may further refine the screening assessment through a site-specific assessment.

In evaluating the potential multipathway risk from emissions of lead compounds, rather than developing a screening threshold emission rate, we compare maximum estimated chronic inhalation exposure concentrations to the level of the current National Ambient Air Quality Standard (NAAQS) for lead.¹⁸ Values below the level of the primary (health-based) lead NAAQS are

considered to have a low potential for multipathway risk. For further information on the multipathway assessment approach, see Appendix 6 of the *Residual Risk Assessment for the Lime Manufacturing Source Category in Support of the Risk and Technology Review 2019 Proposed Rule*, which is available in the docket for this action.

5. How do we conduct the environmental risk screening assessment?

a. Adverse Environmental Effect, Environmental HAP, and Ecological Benchmarks

The EPA conducts a screening assessment to examine the potential for an adverse environmental effect as required under section 112(f)(2)(A) of the CAA. Section 112(a)(7) of the CAA defines "adverse environmental effect" as "any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas."

The EPA focuses on eight HAP, which are referred to as "environmental HAP," in its screening assessment: Six PB-HAP and two acid gases. The PB-HAP included in the screening assessment are arsenic compounds, cadmium compounds, D/F, POM, mercury (both inorganic mercury and methyl mercury), and lead compounds. The acid gases included in the screening assessment are HCl and hydrogen fluoride (HF).

HAP that persist and bioaccumulate are of particular environmental concern because they accumulate in the soil, sediment, and water. The acid gases, HCl and HF, are included due to their well-documented potential to cause direct damage to terrestrial plants. In the environmental risk screening assessment, we evaluate the following four exposure media: Terrestrial soils, surface water bodies (includes water-column and benthic sediments), fish consumed by wildlife, and air. Within these four exposure media, we evaluate nine ecological assessment endpoints, which are defined by the ecological entity and its attributes. For PB-HAP (other than lead), both community-level and population-level endpoints are included. For acid gases, the ecological assessment evaluated is terrestrial plant communities.

An ecological benchmark represents a concentration of HAP that has been linked to a particular environmental effect level. For each environmental

¹⁶ Burger, J. 2002. Daily consumption of wild fish and game: Exposures of high end recreationists. *International Journal of Environmental Health Research* 12:343–354.

¹⁷ U.S. EPA. *Exposure Factors Handbook 2011 Edition (Final)*. U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-09/052F, 2011.

¹⁸ In doing so, the EPA notes that the legal standard for a primary NAAQS—that a standard is requisite to protect public health and provide an adequate margin of safety (CAA section 109(b))—differs from the CAA section 112(f) standard (requiring, among other things, that the standard provide an "ample margin of safety to protect public health"). However, the primary lead NAAQS is a reasonable measure of determining risk acceptability (*i.e.*, the first step of the Benzene NESHAP analysis) since it is designed to protect the most susceptible group in the human population—children, including children living near major lead emitting sources. 73 FR 67002/3; 73 FR 67000/3; 73 FR 67005/1. In addition, applying the level of the primary lead NAAQS at the risk acceptability step is conservative, since that primary lead NAAQS reflects an adequate margin of safety.

HAP, we identified the available ecological benchmarks for each assessment endpoint. We identified, where possible, ecological benchmarks at the following effect levels: Probable effect levels, lowest-observed-adverse-effect level, and no-observed-adverse-effect level. In cases where multiple effect levels were available for a particular PB-HAP and assessment endpoint, we use all of the available effect levels to help us to determine whether ecological risks exist and, if so, whether the risks could be considered significant and widespread.

For further information on how the environmental risk screening assessment was conducted, including a discussion of the risk metrics used, how the environmental HAP were identified, and how the ecological benchmarks were selected, see Appendix 9 of the *Residual Risk Assessment for the Lime Manufacturing Source Category in Support of the Risk and Technology Review 2019 Proposed Rule*, which is available in the docket for this action.

b. Environmental Risk Screening Methodology

For the environmental risk screening assessment, the EPA first determined whether any facilities in the Lime Manufacturing source category emitted any of the environmental HAP. For the Lime Manufacturing source category, we identified emissions of arsenic, D/F, HCl, cadmium, and mercury. Because one or more of the environmental HAP above are emitted by at least one facility in the source category, we proceeded to the second step of the evaluation.

c. PB-HAP Methodology

The environmental screening assessment includes six PB-HAP, arsenic compounds, cadmium compounds, D/F, POM, mercury (both inorganic mercury and methyl mercury), and lead compounds. With the exception of lead, the environmental risk screening assessment for PB-HAP consists of three tiers. The first tier of the environmental risk screening assessment uses the same health-protective conceptual model that is used for the Tier 1 human health screening assessment. TRIM.FaTE model simulations were used to back-calculate Tier 1 screening threshold emission rates. The screening threshold emission rates represent the emission rate in tons per year that results in media concentrations at the facility that equal the relevant ecological benchmark. To assess emissions from each facility in the category, the reported emission rate for each PB-HAP was compared to the Tier 1 screening threshold emission rate

for that PB-HAP for each assessment endpoint and effect level. If emissions from a facility do not exceed the Tier 1 screening threshold emission rate, the facility “passes” the screening assessment, and, therefore, is not evaluated further under the screening approach. If emissions from a facility exceed the Tier 1 screening threshold emission rate, we evaluate the facility further in Tier 2.

In Tier 2 of the environmental screening assessment, the screening threshold emission rates are adjusted to account for local meteorology and the actual location of lakes in the vicinity of facilities that did not pass the Tier 1 screening assessment. For soils, we evaluate the average soil concentration for all soil parcels within a 7.5-km radius for each facility and PB-HAP. For the water, sediment, and fish tissue concentrations, the highest value for each facility for each pollutant is used. If emission concentrations from a facility do not exceed the Tier 2 screening threshold emission rate, the facility “passes” the screening assessment and typically is not evaluated further. If emissions from a facility exceed the Tier 2 screening threshold emission rate, we evaluate the facility further in Tier 3.

As in the multipathway human health risk assessment, in Tier 3 of the environmental screening assessment, we examine the suitability of the lakes around the facilities to support life and remove those that are not suitable (e.g., lakes that have been filled in or are industrial ponds), adjust emissions for plume-rise, and conduct hour-by-hour time-series assessments. If these Tier 3 adjustments to the screening threshold emission rates still indicate the potential for an adverse environmental effect (i.e., facility emission rate exceeds the screening threshold emission rate), we may elect to conduct a more refined assessment using more site-specific information. If, after additional refinement, the facility emission rate still exceeds the screening threshold emission rate, the facility may have the potential to cause an adverse environmental effect.

To evaluate the potential for an adverse environmental effect from lead, we compared the average modeled air concentrations (from HEM-3) of lead around each facility in the source category to the level of the secondary NAAQS for lead. The secondary lead NAAQS is a reasonable means of evaluating environmental risk because it is set to provide substantial protection against adverse welfare effects which can include “effects on soils, water, crops, vegetation, man-made materials,

animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.”

d. Acid Gas Environmental Risk Methodology

The environmental screening assessment for acid gases evaluates the potential phytotoxicity and reduced productivity of plants due to chronic exposure to HF and HCl. The environmental risk screening methodology for acid gases is a single-tier screening assessment that compares modeled ambient air concentrations (from AERMOD) to the ecological benchmarks for each acid gas. To identify a potential adverse environmental effect (as defined in section 112(a)(7) of the CAA) from emissions of HF and HCl, we evaluate the following metrics: the size of the modeled area around each facility that exceeds the ecological benchmark for each acid gas, in acres and km²; the percentage of the modeled area around each facility that exceeds the ecological benchmark for each acid gas; and the area-weighted average screening value around each facility (calculated by dividing the area-weighted average concentration over the 50-km modeling domain by the ecological benchmark for each acid gas). For further information on the environmental screening assessment approach, see Appendix 9 of the *Residual Risk Assessment for the Lime Manufacturing Source Category in Support of the Risk and Technology Review 2019 Proposed Rule*, which is available in the docket for this action.

6. How do we conduct facility-wide assessments?

To put the source category risks in context, we typically examine the risks from the entire “facility,” where the facility includes all HAP-emitting operations within a contiguous area and under common control. In other words, we examine the HAP emissions not only from the source category emission points of interest, but also emissions of HAP from all other emission sources at the facility for which we have data. For this source category, we conducted the facility-wide assessment using a dataset compiled from the 2014 NEI for 31 of the 35 modeled facilities. The remaining four facilities’ emissions data were collected using a combination of approaches, including using permit data and substituting emissions data from similar site(s) (refer to Appendix 1 of the *Residual Risk Assessment for the Lime Manufacturing Source Category in*

Support of the Risk and Technology Review 2019 Proposed Rule, which is available in the docket for this action for further information).

The source category records of the dataset were removed, evaluated, and updated as described in section II.C of this preamble: What data collection activities were conducted to support this action? Once a quality assured source category dataset was available, it was placed back with the remaining records for that facility. The facility-wide file was then used to analyze risks due to the inhalation of HAP that are emitted “facility-wide” for the populations residing within 50 km of each facility, consistent with the methods used for the source category analysis described above. For these facility-wide risk analyses, the modeled source category risks were compared to the facility-wide risks to determine the portion of the facility-wide risks that could be attributed to the source category addressed in this action. We also specifically examined the facility that was associated with the highest estimate of risk and determined the percentage of that risk attributable to the source category of interest. The *Residual Risk Assessment for the Lime Manufacturing Source Category in Support of the Risk and Technology Review 2019 Proposed Rule*, available through the docket for this action, provides the methodology and results of the facility-wide analyses, including all facility-wide risks and the percentage of source category contribution to facility-wide risks.

For this source category, the majority of the facility-wide dataset that the EPA compiled were from the 2014 NEI. We used the NEI data for the facility and did not adjust any category or “non-category” data. Therefore, there could be differences in the dataset from that used for the source category assessments described in this preamble. We analyzed risks due to the inhalation of HAP that are emitted “facility-wide” for the populations residing within 50 km of each facility, consistent with the methods used for the source category analysis described above. For these facility-wide risk analyses, we made a reasonable attempt to identify the source category risks, and these risks were compared to the facility-wide risks to determine the portion of facility-wide risks that could be attributed to the source category addressed in this action. We also specifically examined the facility that was associated with the highest estimate of risk and determined the percentage of that risk attributable to the source category of interest. The *Residual Risk Assessment for the Lime*

Manufacturing Source Category in Support of the Risk and Technology Review 2019 Proposed Rule, available through the docket for this action, provides the methodology and results of the facility-wide analyses, including all facility-wide risks and the percentage of source category contribution to facility-wide risks.

7. How do we consider uncertainties in risk assessment?

Uncertainty and the potential for bias are inherent in all risk assessments, including those performed for this proposal. Although uncertainty exists, we believe that our approach, which used conservative tools and assumptions, ensures that our decisions are health and environmentally protective. A brief discussion of the uncertainties in the RTR emissions dataset, dispersion modeling, inhalation exposure estimates, and dose-response relationships follows below. Also included are those uncertainties specific to our acute screening assessments, multipathway screening assessments, and our environmental risk screening assessments. A more thorough discussion of these uncertainties is included in the *Residual Risk Assessment for the Lime Manufacturing Source Category in Support of the Risk and Technology Review 2019 Proposed Rule*, which is available in the docket for this action. If a multipathway site-specific assessment was performed for this source category, a full discussion of the uncertainties associated with that assessment can be found in Appendix 11 of that document, *Site-Specific Human Health Multipathway Residual Risk Assessment Report*.

a. Uncertainties in the RTR Emissions Dataset

Although the development of the RTR emissions dataset involved quality assurance/quality control processes, the accuracy of emissions values will vary depending on the source of the data, the degree to which data are incomplete or missing, the degree to which assumptions made to complete the datasets are accurate, errors in emission estimates, and other factors. The emission estimates considered in this analysis generally are annual totals for certain years, and they do not reflect short-term fluctuations during the course of a year or variations from year to year. The estimates of peak hourly screening rates for the acute effects screening assessment were based on a default emission adjustment factor of 10 applied to the average annual hourly emission rates, which are intended to

account for emission fluctuations due to normal facility operations.

b. Uncertainties in Dispersion Modeling

We recognize there is uncertainty in ambient concentration estimates associated with any model, including the EPA’s recommended regulatory dispersion model, AERMOD. In using a model to estimate ambient pollutant concentrations, the user chooses certain options to apply. For RTR assessments, we select some model options that have the potential to overestimate ambient air concentrations (e.g., not including plume depletion or pollutant transformation). We select other model options that have the potential to underestimate ambient impacts (e.g., not including building downwash). Other options that we select have the potential to either under- or overestimate ambient levels (e.g., meteorology and receptor locations). On balance, considering the directional nature of the uncertainties commonly present in ambient concentrations estimated by dispersion models, the approach we apply in the RTR assessments should yield unbiased estimates of ambient HAP concentrations. We also note that the selection of meteorology dataset location could have an impact on the risk estimates. As we continue to update and expand our library of meteorological station data used in our risk assessments, we expect to reduce this variability.

c. Uncertainties in Inhalation Exposure Assessment

Although every effort is made to identify all of the relevant facilities and emission points, as well as to develop accurate estimates of the annual emission rates for all relevant HAP, the uncertainties in our emission inventory likely dominate the uncertainties in the exposure assessment. Some uncertainties in our exposure assessment include human mobility, using the centroid of each census block, assuming lifetime exposure, and assuming only outdoor exposures. For most of these factors, there is neither an under nor overestimate when looking at the maximum individual risk or the incidence, but the shape of the distribution of risks may be affected. With respect to outdoor exposures, actual exposures may not be as high if people spend time indoors, especially for very reactive pollutants or larger particles. For all factors, we reduce uncertainty when possible. For example, with respect to census-block centroids, we analyze large blocks using aerial imagery and adjust locations of the block centroids to better represent

the population in the blocks. We also add additional receptor locations where the population of a block is not well represented by a single location.

d. Uncertainties in Dose-Response Relationships

There are uncertainties inherent in the development of the dose-response values used in our risk assessments for cancer effects from chronic exposures and noncancer effects from both chronic and acute exposures. Some uncertainties are generally expressed quantitatively, and others are generally expressed in qualitative terms. We note, as a preface to this discussion, a point on dose-response uncertainty that is stated in the EPA's *2005 Guidelines for Carcinogen Risk Assessment*; namely, that "the primary goal of EPA actions is protection of human health; accordingly, as an Agency policy, risk assessment procedures, including default options that are used in the absence of scientific data to the contrary, should be health protective" (the EPA's *2005 Guidelines for Carcinogen Risk Assessment*, page 1–7). This is the approach followed here as summarized in the next paragraphs.

Cancer UREs used in our risk assessments are those that have been developed to generally provide an upper bound estimate of risk.¹⁹ That is, they represent a "plausible upper limit to the true value of a quantity" (although this is usually not a true statistical confidence limit). In some circumstances, the true risk could be as low as zero; however, in other circumstances the risk could be greater.²⁰ Chronic noncancer RfC and reference dose (RfD) values represent chronic exposure levels that are intended to be health-protective levels. To derive dose-response values that are intended to be "without appreciable risk," the methodology relies upon an uncertainty factor (UF) approach,²¹ which considers uncertainty, variability, and gaps in the available data. The UFs are applied to derive dose-response values that are intended to protect

against appreciable risk of deleterious effects.

Many of the UFs used to account for variability and uncertainty in the development of acute dose-response values are quite similar to those developed for chronic durations. Additional adjustments are often applied to account for uncertainty in extrapolation from observations at one exposure duration (e.g., 4 hours) to derive an acute dose-response value at another exposure duration (e.g., 1 hour). Not all acute dose-response values are developed for the same purpose, and care must be taken when interpreting the results of an acute assessment of human health effects relative to the dose-response value or values being exceeded. Where relevant to the estimated exposures, the lack of acute dose-response values at different levels of severity should be factored into the risk characterization as potential uncertainties.

Uncertainty also exists in the selection of ecological benchmarks for the environmental risk screening assessment. We established a hierarchy of preferred benchmark sources to allow selection of benchmarks for each environmental HAP at each ecological assessment endpoint. We searched for benchmarks for three effect levels (i.e., no-effects level, threshold-effect level, and probable effect level), but not all combinations of ecological assessment/environmental HAP had benchmarks for all three effect levels. Where multiple effect levels were available for a particular HAP and assessment endpoint, we used all of the available effect levels to help us determine whether risk exists and whether the risk could be considered significant and widespread.

Although we make every effort to identify appropriate human health effect dose-response values for all pollutants emitted by the sources in this risk assessment, some HAP emitted by this source category are lacking dose-response assessments. Accordingly, these pollutants cannot be included in the quantitative risk assessment, which could result in quantitative estimates understating HAP risk. To help to alleviate this potential underestimate, where we conclude similarity with a HAP for which a dose-response value is available, we use that value as a surrogate for the assessment of the HAP for which no value is available. To the extent use of surrogates indicates appreciable risk, we may identify a need to increase priority for an IRIS assessment for that substance. We additionally note that, generally speaking, HAP of greatest concern due

to environmental exposures and hazard are those for which dose-response assessments have been performed, reducing the likelihood of understating risk. Further, HAP not included in the quantitative assessment are assessed qualitatively and considered in the risk characterization that informs the risk management decisions, including consideration of HAP reductions achieved by various control options.

For a group of compounds that are unspiciated (e.g., glycol ethers), we conservatively use the most protective dose-response value of an individual compound in that group to estimate risk. Similarly, for an individual compound in a group (e.g., ethylene glycol diethyl ether) that does not have a specified dose-response value, we also apply the most protective dose-response value from the other compounds in the group to estimate risk.

e. Uncertainties in Acute Inhalation Screening Assessments

In addition to the uncertainties highlighted above, there are several factors specific to the acute exposure assessment that the EPA conducts as part of the risk review under section 112 of the CAA. The accuracy of an acute inhalation exposure assessment depends on the simultaneous occurrence of independent factors that may vary greatly, such as hourly emissions rates, meteorology, and the presence of a person. In the acute screening assessment that we conduct under the RTR program, we assume that peak emissions from the source category and reasonable worst-case air dispersion conditions (i.e., 99th percentile) co-occur. We then include the additional assumption that a person is located at this point at the same time. Together, these assumptions represent a reasonable worst-case actual exposure scenario. In most cases, it is unlikely that a person would be located at the point of maximum exposure during the time when peak emissions and reasonable worst-case air dispersion conditions occur simultaneously.

f. Uncertainties in the Multipathway and Environmental Risk Screening Assessments

For each source category, we generally rely on site-specific levels of PB-HAP or environmental HAP emissions to determine whether a refined assessment of the impacts from multipathway exposures is necessary or whether it is necessary to perform an environmental screening assessment. This determination is based on the results of a three-tiered screening assessment that relies on the outputs

¹⁹ IRIS glossary (https://ofmpub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&glossaryName=IRIS%20Glossary).

²⁰ An exception to this is the URE for benzene, which is considered to cover a range of values, each end of which is considered to be equally plausible, and which is based on maximum likelihood estimates.

²¹ See *A Review of the Reference Dose and Reference Concentration Processes*, U.S. EPA, December 2002, and *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry*, U.S. EPA, 1994.

from models—TRIM.FaTE and AERMOD—that estimate environmental pollutant concentrations and human exposures for five PB-HAP (D/F, POM, mercury, cadmium, and arsenic) and two acid gases (hydrogen fluoride and hydrogen chloride). For lead, we use AERMOD to determine ambient air concentrations, which are then compared to the secondary NAAQS standard for lead. Two important types of uncertainty associated with the use of these models in RTR risk assessments and inherent to any assessment that relies on environmental modeling are model uncertainty and input uncertainty.²²

Model uncertainty concerns whether the model adequately represents the actual processes (e.g., movement and accumulation) that might occur in the environment. For example, does the model adequately describe the movement of a pollutant through the soil? This type of uncertainty is difficult to quantify. However, based on feedback received from previous EPA SAB reviews and other reviews, we are confident that the models used in the screening assessments are appropriate and state-of-the-art for the multipathway and environmental screening risk assessments conducted in support of RTR.

Input uncertainty is concerned with how accurately the models have been configured and parameterized for the assessment at hand. For Tier 1 of the multipathway and environmental screening assessments, we configured the models to avoid underestimating exposure and risk. This was accomplished by selecting upper-end values from nationally representative datasets for the more influential parameters in the environmental model, including selection and spatial configuration of the area of interest, lake location and size, meteorology, surface water, soil characteristics, and structure of the aquatic food web. We also assume an ingestion exposure scenario and values for human exposure factors that represent reasonable maximum exposures.

In Tier 2 of the multipathway and environmental screening assessments, we refine the model inputs to account for meteorological patterns in the vicinity of the facility versus using upper-end national values, and we identify the actual location of lakes near

the facility rather than the default lake location that we apply in Tier 1. By refining the screening approach in Tier 2 to account for local geographical and meteorological data, we decrease the likelihood that concentrations in environmental media are overestimated, thereby increasing the usefulness of the screening assessment. In Tier 3 of the screening assessments, we refine the model inputs again to account for hour-by-hour plume rise and the height of the mixing layer. We can also use those hour-by-hour meteorological data in a TRIM.FaTE run using the screening configuration corresponding to the lake location. These refinements produce a more accurate estimate of chemical concentrations in the media of interest, thereby reducing the uncertainty with those estimates. The assumptions and the associated uncertainties regarding the selected ingestion exposure scenario are the same for all three tiers.

For the environmental screening assessment for acid gases, we employ a single-tiered approach. We use the modeled air concentrations and compare those with ecological benchmarks.

For all tiers of the multipathway and environmental screening assessments, our approach to addressing model input uncertainty is generally cautious. We choose model inputs from the upper end of the range of possible values for the influential parameters used in the models, and we assume that the exposed individual exhibits ingestion behavior that would lead to a high total exposure. This approach reduces the likelihood of not identifying high risks for adverse impacts.

Despite the uncertainties, when individual pollutants or facilities do not exceed screening threshold emission rates (i.e., screen out), we are confident that the potential for adverse multipathway impacts on human health is very low. On the other hand, when individual pollutants or facilities do exceed screening threshold emission rates, it does not mean that impacts are significant, only that we cannot rule out that possibility and that a refined assessment for the site might be necessary to obtain a more accurate risk characterization for the source category.

The EPA evaluates the following HAP in the multipathway and/or environmental risk screening assessments, where applicable: Arsenic, cadmium, D/F, lead, mercury (both inorganic and methyl mercury), POM, HCl, and HF. These HAP represent pollutants that can cause adverse impacts either through direct exposure to HAP in the air or through exposure to HAP that are deposited from the air

onto soils and surface waters and then through the environment into the food web. These HAP represent those HAP for which we can conduct a meaningful multipathway or environmental screening risk assessment. For other HAP not included in our screening assessments, the model has not been parameterized such that it can be used for that purpose. In some cases, depending on the HAP, we may not have appropriate multipathway models that allow us to predict the concentration of that pollutant. The EPA acknowledges that other HAP beyond these that we are evaluating may have the potential to cause adverse effects and, therefore, the EPA may evaluate other relevant HAP in the future, as modeling science and resources allow.

IV. Analytical Results and Proposed Decisions

A. What are the results of the risk assessment and analyses?

As described above, for the Lime Manufacturing source category we conducted an inhalation risk assessment for all HAP emitted, a multipathway screening assessment for the PB-HAP emitted, and an environmental risk screening assessment for the PB-HAP and HCl emitted from the source category. We present results of the risk assessment briefly below and in more detail in the *Residual Risk Assessment for the Lime Manufacturing Source Category in Support of the Risk and Technology Review 2019 Proposed Rule*, which is available in the docket for this action.

1. Inhalation Risk Assessment Results

The EPA estimated inhalation risk based on actual and allowable emissions. The estimated baseline maximum inhalation cancer risk (MIR) posed by the source category is 1-in-1 million based on actual emissions and 2-in-1 million based upon MACT-allowable emissions. The total estimated cancer incidence based on actual emission levels is 0.001 excess cancer cases per year, or one case every 1,000 years. The total estimated cancer incidence based on allowable emission levels is 0.003 excess cancer cases per year, or one case every 333 years. Emissions of metals, aldehydes, and organic HAP from the lime kiln and cooler exhaust accounted for 93 percent to the cancer incidence. The estimated population exposed to cancer risk of 1-in-1 million based upon actual emissions is 12 (see Table 2 of this preamble).

The maximum chronic noncancer TOSHI values for the source category

²² In the context of this discussion, the term “uncertainty” as it pertains to exposure and risk encompasses both *variability* in the range of expected inputs and screening results due to existing spatial, temporal, and other factors, as well as *uncertainty* in being able to accurately estimate the true result.

were estimated to be less than 1 (0.04) based on actual emissions and less than 1 (0.05) based upon allowable

emissions. For both actual and allowable emissions, respiratory risks were driven by HCl, nickel compounds,

and acrolein emissions from lime kiln and cooler exhaust.

TABLE 2—INHALATION RISK ASSESSMENT SUMMARY FOR LIME MANUFACTURING ¹ SOURCE CATEGORY
[40 CFR Part 63, Subpart AAAAA]

Risk assessment	Number of facilities ²	Maximum individual cancer risk (1-in-1 million) ³	Estimated population at increased risk of cancer ≥ 1-in-1 million	Estimated annual cancer incidence (cases per yr)	Maximum chronic noncancer TOSHI ⁴	Maximum screening acute non-cancer HQ ⁵
Baseline Actual Emissions:						
Source Category	35	1	12	0.001	0.04 (respiratory)	0.6 (REL)
Facility-Wide	35	1	30	0.004	0.4 (respiratory) ..	
Baseline Allowable Emissions:						
Source Category	35	2	450	0.003	0.05 (respiratory)	

¹ Based on actual and allowable emissions.

² Number of facilities evaluated in the risk assessment. Includes 35 operating facilities subject to subpart AAAAA.

³ Maximum individual excess lifetime cancer risk due to HAP emissions from the source category.

⁴ Maximum TOSHI. The target organ with the highest TOSHI for the Lime Manufacturing source category is the respiratory system.

⁵ The maximum estimated acute exposure concentration was divided by available short-term threshold values to develop an array of HQ values. The acute HQ shown was based upon the lowest acute 1 hour dose-response value, the REL for elemental mercury. When an HQ exceeds 1, we also show the HQ using the next lowest available acute dose-response value.

2. Screening Level Acute Risk Assessment Results

Based on our screening analysis of reasonable worst-case acute exposure to actual emissions from the category, no HAP exposures result in an HQ greater than 1 (0.6) based upon the 1- hour REL. As discussed in section III.C.3.c of this preamble, we used the default acute hourly multiplier of 10 for all emission processes.

3. Multipathway Risk Screening Results

PB–HAP emissions (based on estimates of actual emissions) from all 35 facilities in the source category exceed the Tier 1 screening threshold emission rates for the carcinogenic PB–HAP, D/F, and arsenic. Emissions from 34 of the 35 facilities exceed the Tier 1 screening threshold emission rate for mercury, a PB–HAP with noncancer health effects. Cadmium emissions from all but one facility were below the Tier 1 noncancer screening threshold emission rate. For the PB–HAP and facilities with Tier 1 screening values greater than 1, we conducted a Tier 2 screening analysis.

D/F and arsenic emissions from 26 facilities exceeded the Tier 2 cancer screening value of 1. The Tier 2 fisher scenario resulted in a maximum cancer screening value of 20 with D/F emissions driving the risk. The Tier 2 farmer scenario resulted in a maximum cancer screening value of 20 due to both arsenic and D/F emissions. For cadmium, the Tier 2 noncancer screening value (0.1) did not exceed 1. Mercury emissions from 16 facilities had Tier 2 noncancer screening values greater than 1 under the fisher scenario, with the largest Tier 2 screen value

equal to 4. When we evaluated the effect multiple facilities within the source category could have on common lake(s) in the modeling domain, mercury emissions exceeded the noncancer screening value by a factor of 5.

For mercury, we continued the fisher scenario screening analysis with a Tier 3 multipathway screen which comprises three individual stages. These stages included lake, plume rise, and time-series assessments. Tier 3 lake and plume rise assessments were conducted for all facilities with Tier 2 mercury screening values greater than 1. A Tier 3 time series screen was conducted for the facility with the highest mercury non-cancer screening value after conducting the lake and plume rise assessments. After conducting the time series screen, the facility evaluated had a Tier 3 non-cancer screening value of 2 for mercury, including consideration of cumulative lake impacts from facilities within the source category.

One of the facilities evaluated in the Tier 3 plume-rise screen for mercury also had the highest Tier 2 cancer screening value under the fisher scenario, 20 for D/F. The refined Tier 3 plume rise assessment for this facility resulted in a cancer screening value of 10. This cancer screening value of 10 for the fisher scenario is the highest for the source category. Further details on the Tier 3 screening analysis can be found in Appendix 11 of *Residual Risk Assessment for the Lime Manufacturing Source Category in Support of the Risk and Technology Review 2019 Proposed Rule*.

A screening value in any of the tiers is not an estimate of the cancer risk or

a noncancer HQ (or HI). Rather, a screening value represents a high-end estimate of what the risk or HQ may be. For example, facility emissions resulting in a screening value of 2 for a non-carcinogen can be interpreted to mean that we are confident that the HQ would be lower than 2. Similarly, facility emissions resulting in a cancer screening value of 20 for a carcinogen means that we are confident that the cancer risk is lower than 20-in-1 million. Our confidence comes from the health-protective assumptions that are incorporated into the screens: We choose inputs from the upper end of the range of possible values for the influential parameters used in the screens and we assume food consumption behaviors that would lead to high total exposure. This risk assessment estimates the maximum hazard for mercury through fish consumption based on upper bound screens and the maximum excess cancer risks from D/F and arsenic through ingestion of fish and farm produce.

When we progress from the model designs of the Tier 1, 2, and 3 screens to a site-specific assessment, we refine the risk assessment through incorporation of additional site-specific data and enhanced model designs. Site-specific refinements include the following: (1) improved spatial locations identifying the boundaries of the watershed and lakes within the watershed as they relate to surrounding facilities within the source category; (2) calculating actual soil/water run-off amounts to target lakes based upon actual soil type(s) and elevation changes associated with the affected watershed versus assuming a worst-case

assumption of 100-percent run-off to target lakes; and (3) incorporating AERMOD deposition of pollutants into TRIM.FaTE to accurately account for site-specific release parameters such as stack heights and exit gas temperatures, versus using TRIM.FaTE's simple dispersion algorithms that assume the pollutant is uniformly distributed within the airshed. These refinements have the net effect of improved modeling of the mass of HAP entering a lake by more accurately defining the watershed/lake boundaries as well as the dispersion of HAP into the atmosphere to better reflect deposition contours across all target watersheds and lakes in our 50 km model domain.

As discussed above, the maximum mercury Tier 2 non-cancer screening value for this source category is 5 with subsequent refinement resulting in a Tier 3 screening value of 2. The EPA has determined that it is not necessary to go beyond the Tier 3 assessment to a site-specific assessment. As explained above, the screening value of 2 is a high-end estimate of what the risk or hazard may be and can be interpreted to mean that we are confident that the HQ would be lower than 2. Further, risk results from three site-specific mercury assessments the EPA has conducted for three RTR source categories resulted in noncancer HQs that were at least 50 times lower than the respective Tier 2 screening value for these facilities (refer to EPA Docket ID No.: 2017–HQ–OAR–2017–0015 for a copy of these reports).²³ Based on our review of these analyses, we would expect at least a one order of magnitude decrease in all Tier 2 noncancer screening values for mercury for the Lime Manufacturing source category, if we were to perform a site-specific assessment. In addition, based upon the conservative nature of the screens and the level of additional refinements that would go into a site-specific multipathway assessment, were one to be conducted, we are confident that the HI for ingestion exposure, specifically mercury through fish ingestion, is less than 1. Further details on the Tier 3 screening assessment can

be found in Appendix 11 of *Residual Risk Assessment for the Lime Manufacturing Source Category in Support of the Risk and Technology Review 2019 Proposed Rule*.

In evaluating the potential for multipathway effects from emissions of lead, the EPA compared modeled annual lead concentrations to the secondary NAAQS level for lead (0.15 µg/m³, arithmetic mean concentration over a 3-month period). The highest annual average lead concentration, of 0.0007 µg/m³, is below the NAAQS level for lead, indicating a low potential for multipathway impacts.

4. Environmental Risk Screening Results

As described in section III.A of this preamble, we conducted an environmental risk screening assessment for the Lime Manufacturing source category for the following pollutants: arsenic, cadmium, D/F, HCl, hydrofluoric acid, lead, mercury (methyl mercury and mercuric chloride), and POM.

In the Tier 1 screening analysis for PB–HAP (other than lead, which was evaluated differently), arsenic, cadmium, and POM emissions had no exceedances of any of the ecological benchmarks evaluated. D/F emissions had a Tier 1 exceedance at 31 facilities for a surface soil no-observed-adverse-effect-level (NOAEL) (mammalian insectivores—shrew) by a maximum screening value of 30. Divalent mercury emissions had Tier 1 exceedances for the following benchmarks: Sediment threshold level (one facility), surface soil threshold level—plant communities (25 facilities), and surface soil threshold level—invertebrate communities (32 facilities) by a maximum screening value of 20. Methyl mercury emissions had Tier 1 exceedances for the following benchmarks: Fish (avian/piscivores) NOAEL—Merganser (one facility), surface soil NOAEL for mammalian insectivores—shrew (13 facilities), and surface soil NOAEL for avian ground insectivores—woodcock (33 facilities) by a maximum screening value of 40.

A Tier 2 screening analysis was performed for D/F, divalent mercury, and methyl mercury emissions. In the Tier 2 screening analysis, there were no exceedances of any of the ecological benchmarks evaluated for any of the pollutants.

For lead, we did not estimate any exceedances of the secondary lead NAAQS. For HCl and HF, the average modeled concentration around each

facility (*i.e.*, the average concentration of all off-site data points in the modeling domain) did not exceed any ecological benchmark. In addition, each individual modeled concentration of HCl and HF (*i.e.*, each off-site data point in the modeling domain) was below the ecological benchmarks for all facilities.

Based on the results of the environmental risk screening analysis, we do not expect an adverse environmental effect as a result of HAP emissions from this source category.

5. Facility-Wide Risk Results

The maximum lifetime individual cancer risk posed by the 35 facilities, based on facility-wide emissions, is 1-in-1 million (estimated for three facilities), with arsenic, chromium (VI) compounds, and nickel emissions from fugitive PSH operations driving the risk. The total estimated cancer incidence from facility-wide emissions is 0.004 excess cancer cases per year, or one case in every 250 years. Approximately 30 people are estimated to have cancer risk equal to 1-in-1 million from facility-wide emissions. The maximum facility-wide chronic noncancer TOSHI is estimated to be less than 1 (0.4), mainly driven by emissions of HCl from a facility-wide fugitive area source.

6. What demographic groups might benefit from this regulation?

To examine the potential for any environmental justice issues that might be associated with the source category, we performed a demographic analysis, which is an assessment of risk to individual demographic groups of the populations living within 5 km and within 50 km of the facilities. In the analysis, we evaluated the distribution of HAP-related cancer and noncancer risk from the Lime Manufacturing source category across different demographic groups within the populations living near facilities.²⁴

The results of the demographic analysis are summarized in Table 3 below. These results, for various demographic groups, are based on the estimated risk from actual emissions levels for the population living within 50 km of the facilities.

²⁴ Demographic groups included in the analysis are: White, African American, Native American, other races and multiracial, Hispanic or Latino, children 17 years of age and under, adults 18 to 64 years of age, adults 65 years of age and over, adults without a high school diploma, people living below the poverty level, people living two times the poverty level, and linguistically isolated people.

²³ EPA Docket records: Appendix 11 of the *Residual Risk Assessment for the Integrated Iron and Steel Source Category in Support of the Risk and Technology Review 2019 Proposed Rule*; Appendix 11 of the *Residual Risk Assessment for the Portland Cement Manufacturing Source Category in Support of the 2018 Risk and Technology Review Final Rule*; and Appendix 11 of the *Residual Risk Assessment for the Coal and Oil-Fired EGU Source Category in Support of the 2018 Risk and Technology Review Proposed Rule*.

TABLE 3—LIME MANUFACTURING SOURCE CATEGORY DEMOGRAPHIC RISK ANALYSIS RESULTS

	Population with cancer risk at or above 1-in-1 million due to lime manufacturing		Population with chronic hazard index above 1 due to lime manufacturing
	Nationwide	Source category	
Total Population	317,746,049	12	0
Race by Percent			
White	62	75	0
All Other Races	38	25	0
Race by Percent			
Hispanic or Latino (includes white and nonwhite)	62	75	0
African American	12	17	0
Native American	0.8	0	0
Other and Multiracial	7	0	0
Income by Percent			
Below Poverty Level	14	17	0
Above Poverty Level	86	83	0
Education by Percent			
Over 25 and without a High School Diploma	14	22	0
Over 25 and with a High School Diploma	86	78	0
Linguistically Isolated by Percent			
Linguistically Isolated	6	0	0

The results of the Lime Manufacturing source category demographic analysis indicate that emissions from the source category expose approximately 12 people to a cancer risk at or above 1-in-1 million and no people to a chronic noncancer TOSHI greater than 1. The percentages of the at-risk population indicate that three of the 10 demographic groups (White, African American and people below the poverty level) that are living within 50 km of facilities in the source category exceed the corresponding national percentage for the same demographic groups.

The methodology and the results of the demographic analysis are presented in a technical report, *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Lime Manufacturing Source Category Operations*, available in the docket for this action.

B. What are our proposed decisions regarding risk acceptability, ample margin of safety, and adverse environmental effect?

1. Risk Acceptability

As explained in section II.A of this preamble, the EPA sets standards under CAA section 112(f)(2) using “a two-step standard-setting approach, with an

analytical first step to determine an ‘acceptable risk’ that considers all health information, including risk estimation uncertainty, and includes a presumptive limit on MIR of approximately 1-in-10 thousand” (54 FR 38045, September 14, 1989). The EPA weighed all health risk measures and information, including science policy assumptions and estimation uncertainties, in determining whether risk posed by emissions from the source category is acceptable.

The maximum cancer risk for inhalation exposure to actual emissions from the Lime Manufacturing source category (1-in-1 million) is two orders of magnitude below 100-in-1 million, which is the presumptive upper limit of acceptable risk. The maximum inhalation cancer risk based on MACT allowable emissions (2-in-1 million) is similar. The EPA estimates emissions from the category would result in a cancer incidence of 0.001 excess cancer cases per year, or one case every 1,000 years. Twelve individuals are estimated to have inhalation cancer risk equal to 1-in-1 million. Inhalation exposures to HAP associated with chronic noncancer health effects result in a TOSHI of 0.04 based on actual emissions, 25 times below an exposure that the EPA has

estimated is without appreciable risk of adverse health effects. Exposures to HAP associated with acute noncancer health effects also are below levels of health concern with no HAP exposures resulting in an HQ greater than 1 (0.6) based upon the 1-hour REL.

Maximum cancer risk due to ingestion exposures estimated using health-protective risk screening assumptions are below 10-in-1 million for the Tier 3 fisher scenario and below 20-in-1 million for the Tier 2 farmer exposure scenario. The Tier 3 noncancer screening analyses of mercury exposure due to fish ingestion determined that the maximum HQ for mercury would be less than 2, as explained in section III.C.4 of this preamble. The EPA is confident that this hazard estimate would be reduced to a HQ of less than 1 if further refined to incorporate enhanced site-specific analyses such as improved model boundary identification with improved soil/water run-off calculations and AERMOD deposition outputs used in the TRIM.FaTE model. Considering all of the health risk information and factors discussed above, as well as the uncertainties discussed in section III of this preamble, we propose that the risks posed by emissions from the Lime

Manufacturing source category are acceptable.

2. Ample Margin of Safety Analysis

As directed by CAA section 112(f)(2), we conducted an analysis to determine whether the current emissions standards provide an ample margin of safety to protect public health. Under the ample margin of safety analysis, we evaluated the cost and feasibility of available control technologies and other measures (including the controls, measures, and costs reviewed under the technology review) that could be applied to this source category to further reduce the risks (or potential risks) due to emissions of HAP from the source category. In this analysis, we considered the results of the technology review, risk assessment, and other aspects of our MACT rule review to determine whether there are any measures that would reduce risk further.

Although we are proposing that the risks from this source category are acceptable, risk estimates for approximately 12 people in the exposed population are equal to 1-in-1 million, caused by chromium (VI) compounds, arsenic, nickel, and cadmium emissions (see Table 2 of this preamble). Lime kiln and cooler exhaust emissions result in 93 percent of the cancer incidence for this source category. The NESHAP controls PM as a surrogate for non-mercury HAP metals. Our technology review did not identify any practices, controls, or process options that are being used in this industry that would result in further reduction of PM emissions.²⁵

For D/F and mercury emissions, activated carbon injection (ACI) systems installed prior to the PM control device were identified as a potential control technology. We found that ACI systems have been used on municipal waste combustors, medical waste incinerators, and cement kilns. Experience with ACI on municipal waste combustors and medical waste incinerators led the EPA to develop emission limits for D/F emissions for these sources in the range of 0.26 to 2.5 nanograms as toxic equivalents per dry standard cubic meter (ng TEQ/dscm). These D/F emission levels are well above the D/F emission levels (0.008 to 0.0148 ng TEQ/dscm) that have been measured from lime kilns. Total annual costs for an ACI system, installed prior to the existing PM control device, are estimated to be \$137,000 per lime kiln. Based on the cost and considering the

potential negligible reduction of the already low measured D/F emissions, we do not consider the use of ACI systems to be cost effective for the industry to further reduce D/F emissions. The use of ACI systems would have little effect on the source category risks.

As for mercury emissions, ACI is used on cement kilns which are similar to lime kilns in design, fuel combusted, and feed material. In the RTR conducted for the portland cement manufacturing industry, we estimated that for a typical cement kiln that the addition of an ACI system would result in a 2.3 to 3.0 lb per year reduction in mercury (see 82 FR 44277). Assuming a similar reduction in mercury emissions would be achieved for a typical lime kiln, the cost effectiveness of an ACI system installed prior to the PM control device would be \$46,000 to \$60,000 per lb of mercury removed. Thus, we do not consider the use of ACI systems to be cost effective for the industry to use to further reduce mercury emissions. Our risk analysis indicated the noncancer risks from mercury are low and any further risk reduction from the use of ACI would be minimal.

Because no additional cost-effective measures were identified to further reduce HAP risk from affected sources in the Lime Manufacturing source category, we are proposing that the current NESHAP provides an ample margin of safety to protect public health.

3. Adverse Environmental Effect

Based on the results of our environmental risk screening, we do not anticipate an adverse environmental effect as a result of HAP emissions from this source category and we are proposing that it is not necessary to set a more stringent standard to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.

C. What are the results and proposed decisions based on our technology review?

The RBLC provides several options for searching the permit database online to locate applicable control technologies. We searched the RBLC database for RBL determinations made during the time period between this NESHAP promulgation date (January 05, 2004) and the date the RBLC search was conducted (August 27, 2018). Search results showed a total of 17 facilities with RBL determinations during the 2004–2018 time frame. These results were reviewed to identify any developments in practices, processes, or control technologies related to reducing

emissions of PM from lime kilns and PSH operations.

The primary controls identified were the use of fabric filters to control PM emissions from stacks and the use of water (wet suppression) for the control of PM emissions from fugitive PSH operations. These methods of control served as the basis for standards promulgated in the original NESHAP. The results of the RBLC search did not identify developments in practices, processes, or control technologies for the Lime Manufacturing source category under CAA section 112(d)(6).

To identify developments in emission control strategies, the following questions were asked as part of the January 2017 ICR:

- Do you use any alternative control devices (*i.e.*, control devices other than fabric filters, electrostatic precipitators (ESPs), or wet scrubbers), monitoring procedures, or operating conditions at this facility?
- Do you have any plans to install any new higher efficiency rated control devices or have any pending applications to add on any new controls?
- Describe any procedures you use at your facility to prevent pollution (as opposed to controlling pollution after it is formed).
- Have you implemented any work practice standards or standard operating procedures that will further reduce HAP emissions?

The responses to this inquiry did not identify any developments in practices, processes, or control technologies that would warrant revision to the existing emission standards for the Lime Manufacturing source category.

This review did not identify any developments in practices, processes, or control technologies for PM that have been implemented in this source category since promulgation of the current NESHAP in January of 2004. Consequently, we propose that no revisions to the NESHAP are necessary pursuant to CAA section 112(d)(6). For a detailed discussion of the findings, refer to the *Technology Review for the Lime Manufacturing Source Category* memorandum in the docket.

D. What other actions are we proposing?

In addition to the proposed actions described above, we are proposing additional revisions to the NESHAP. We are proposing revisions to the SSM provisions of the MACT rule in order to ensure that they are consistent with the Court decision in *Sierra Club v. EPA*, 551 F. 3d 1019 (D.C. Cir. 2008), which vacated two provisions that exempted sources from the requirement to comply

²⁵ *Technology Review for the Lime Manufacturing Source Category*; see Docket ID No. EPA–HQ–OAR–2017–0015.

with otherwise applicable CAA section 112(d) emission standards during periods of SSM. We also are proposing to require electronic reporting of Notification of Compliance Status reports, semiannual compliance reports, and performance test reports. Our analyses and proposed changes related to these issues are discussed below.

1. SSM

In its 2008 decision in *Sierra Club v. EPA*, 551 F.3d 1019 (D.C. Cir. 2008), the Court vacated portions of two provisions in the EPA's CAA section 112 regulations governing the emissions of HAP during periods of SSM. Specifically, the Court vacated the SSM exemption contained in 40 CFR 63.6(f)(1) and 40 CFR 63.6(h)(1), holding that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature and that the SSM exemption violates the CAA's requirement that some section 112 standards apply continuously.

We are proposing the elimination of the SSM exemption in this rule, which appears at 40 CFR 63.7100 and in Table 8 to subpart AAAAA of part 63. Consistent with *Sierra Club v. EPA*, we are proposing standards in this rule that apply at all times. We are also proposing several revisions to Table 8 (the General Provisions Applicability Table) as is explained in more detail below. For example, we are proposing to eliminate the incorporation of the General Provisions' requirement that the source develop an SSM plan. We also are proposing to eliminate and revise certain recordkeeping and reporting requirements related to the SSM exemption as further described below.

The EPA has attempted to ensure that the provisions we are proposing to eliminate are inappropriate, unnecessary, or redundant in the absence of the SSM exemption. We are specifically seeking comment on whether we have successfully done so. The EPA believes the removal of the SSM exemption creates no additional burden to facilities regulated under the Lime Manufacturing Plants NESHAP. Deviations currently addressed by a facility's SSM plan are required to be reported in the Semiannual Compliance Report, a requirement that remains under the proposal (40 CFR 63.7130). Facilities will no longer need to develop an SSM plan or keep it current (Table 8, 40 CFR part 63, subpart AAAAA).

In proposing the standards in this rule, the EPA has taken into account startup and shutdown periods and, for the reasons explained below, is proposing alternate standards for those periods.

The EPA has made the determination under CAA section 112(h) that for kilns and coolers it is not feasible to prescribe or enforce a numeric standard during periods of startup and shutdown because the application of measurement methodology is impracticable due to technological and economic limitations. The test methods required for demonstrating compliance are required to be conducted under isokinetic conditions (*i.e.*, steady-state conditions in terms of exhaust gas temperature, moisture, flow rate), which is difficult to achieve during periods of startup and shutdown where conditions are constantly changing. In addition, information²⁶ provided on the amount of time required for startup and shutdown of lime kilns indicates that the application of measurement methodology for these sources using the required procedures, which would require more hours (6) in startup or shutdown mode to satisfy the sample volume requirements in the rule, is impracticable. Upon review of this information, the EPA determined that it is not feasible to require stack testing, in particular, to complete the multiple required test runs during periods of startup and shutdown due to physical limitations and the short duration of startup and shutdown periods. Based on these specific facts for the Lime Manufacturing source category, we are proposing work practice standards for these periods.

The EPA is proposing to require sources to vent emissions to the main stack and operate all control devices necessary to meet the normal operating limits under this NESHAP (with the exception of ESPs) when firing fuel in the lime kiln during startup and shutdown. We are proposing that startup ends 1 hour after lime is produced from the kiln.

Stakeholders in several source categories have expressed concerns that the requirement for engaging applicable control devices does not accommodate potential safety problems associated with ESP operation. Recommended manufacturer operating procedures provided to the EPA during rulemaking for the Industrial, Commercial, and Institutional Boilers and Process Heaters NESHAP explained the potential hazards associated with ESP energization when unburned fuel may exist in the presence of oxygen levels high enough that the mixture can be in the flammable range. In addition, the stakeholders claim that the ESP cannot

practically be engaged until a certain flue gas temperature is reached. Specifically, they claim that premature starting of this equipment will lead to short-term stability problems that could result in unsafe operations and longer term degradation of ESP performance due to fouling, increased chances of wire damage, or increased corrosion within the chambers. They also state that vendors providing this equipment incorporate these safety and operational concerns into their standard operating procedures. For example, they claim that some ESPs have oxygen sensors and alarms that shut down the ESP at high flue gas oxygen levels to avoid a fire in the unit. The oxygen level is typically high during startup, so the ESP may not engage due to these safety controls until more stable operating conditions are reached. These stakeholder claims are supported by a guidance document²⁷ prepared by a trade association of companies that supply air pollution control equipment. Therefore, the EPA is proposing an alternate work practice requirement for operating ESP control devices during periods of startup as follows: Lime kilns owners and operators shall, when firing fuel, vent emissions to the main stack and engage the ESP within 1 hour after the inlet exhaust temperature to the ESP reaches 300 degrees Fahrenheit.

In order to clarify that the work practice does not supersede any other standard or requirements to which the affected source is subject, the EPA is including in the proposed alternate work practice provision a requirement that control devices operate when necessary to comply with other standards (*e.g.*, new source performance standards, state regulations) applicable to the source.

In addition, to ensure compliance with the proposed definition of startup and the work practice standard that applies during startup periods, we are proposing that certain events and parameters be monitored and recorded during the startup periods. These events include the time when firing (*i.e.*, feeding) starts for fuel and limestone; the time when lime is produced; and the time when the PM controls are engaged. The parameters to be monitored and recorded during each startup period include the hourly flue gas temperature and all hourly average continuous monitoring system data (*e.g.*, opacity, ESP total secondary electric power input, scrubber liquid flow rate) to

²⁶ *Lime Kiln Principles and Operations*, Terry N. Adams, <https://www.tappi.org/content/events/08Kros/manuscripts/2.2.pdf>.

²⁷ *Guidance Document on Startup and Shutdown under MATS*, Institute of Clean Air Companies, July 2015.

confirm that the control devices are engaged.

We request comments on the proposed startup and shutdown provisions (definitions and work practices).

Periods of startup, normal operations, and shutdown are all predictable and routine aspects of a source's operations. Malfunctions, in contrast, are neither predictable nor routine. Instead they are, by definition, sudden, infrequent, and not reasonably preventable failures of emissions control, process, or monitoring equipment. (40 CFR 63.2, definition of malfunction). The EPA interprets CAA section 112 as not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112 standards and this reading has been upheld as reasonable by the Court in *U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 606–610 (2016). Under CAA section 112, emissions standards for new sources must be no less stringent than the level “achieved” by the best controlled similar source and for existing sources generally must be no less stringent than the average emission limitation “achieved” by the best performing 12 percent of sources in the category. There is nothing in CAA section 112 that directs the Agency to consider malfunctions in determining the level “achieved” by the best performing sources when setting emission standards. As the Court has recognized, the phrase “average emissions limitation achieved by the best performing 12 percent of” sources “says nothing about how the performance of the best units is to be calculated.” *National Association of Clean Water Agencies v. EPA*, 734 F.3d 1115, 1141 (D.C. Cir. 2013). While the EPA accounts for variability in setting emissions standards, nothing in CAA section 112 requires the Agency to consider malfunctions as part of that analysis. The EPA is not required to treat a malfunction in the same manner as the type of variation in performance that occurs during routine operations of a source. A malfunction is a failure of the source to perform in “normal or usual manner” and no statutory language compels the EPA to consider such events in setting CAA section 112 standards.

As the Court recognized in *U.S. Sugar Corp.*, accounting for malfunctions in setting standards would be difficult, if not impossible, given the myriad different types of malfunctions that can occur across all sources in the category and given the difficulties associated with predicting or accounting for the frequency, degree, and duration of

various malfunctions that might occur. *Id.* at 608 (“the EPA would have to conceive of a standard that could apply equally to the wide range of possible boiler malfunctions, ranging from an explosion to minor mechanical defects. Any possible standard is likely to be hopelessly generic to govern such a wide array of circumstances.”) As such, the performance of units that are malfunctioning is not “reasonably” foreseeable. See, for example, *Sierra Club v. EPA*, 167 F.3d 658, 662 (D.C. Cir. 1999). “The EPA typically has wide latitude in determining the extent of data gathering necessary to solve a problem. We generally defer to an agency’s decision to proceed on the basis of imperfect scientific information, rather than to ‘invest the resources to conduct the perfect study’.” See also, *Weyerhaeuser v. Costle*, 590 F.2d 1011, 1058 (D.C. Cir. 1978), “In the nature of things, no general limit, individual permit, or even any upset provision can anticipate all upset situations. After a certain point, the transgression of regulatory limits caused by ‘uncontrollable acts of third parties,’ such as strikes, sabotage, operator intoxication or insanity, and a variety of other eventualities, must be a matter for the administrative exercise of case-by-case enforcement discretion, not for specification in advance by regulation.” In addition, emissions during a malfunction event can be significantly higher than emissions at any other time of source operation. For example, if an air pollution control device with 99-percent removal goes offline as a result of a malfunction (as might happen if, for example, the bags in a baghouse catch fire) and the emission unit is a steady state type unit that would take days to shut down, the source would go from 99-percent control to zero control until the control device was repaired. The source’s emissions during the malfunction would be 100 times higher than during normal operations. As such, the emissions over a 4-day malfunction period would exceed the annual emissions of the source during normal operations. As this example illustrates, accounting for malfunctions could lead to standards that are not reflective of (and significantly less stringent than) levels that are achieved by a well-performing non-malfunctioning source. It is reasonable to interpret CAA section 112 to avoid such a result. The EPA’s approach to malfunctions is consistent with CAA section 112 and is a reasonable interpretation of the statute.

Although no statutory language compels the EPA to set standards for malfunctions, the EPA has the

discretion to do so where feasible. For example, in the Petroleum Refinery Sector RTR, the EPA established a work practice standard for unique types of malfunction that result in releases from pressure relief devices or emergency flaring events because information was available to determine that such work practices reflected the level of control that applies to the best performers (80 FR 75178, 75211–14; December 1, 2015). The EPA will consider whether circumstances warrant setting standards for a particular type of malfunction and, if so, whether the EPA has sufficient information to identify the relevant best performing sources and establish a standard for such malfunctions. We also encourage commenters to provide any such information.

In the event that a source fails to comply with the applicable CAA section 112(d) standards as a result of a malfunction event, the EPA would determine an appropriate response based on, among other things, the good faith efforts of the source to minimize emissions during malfunction periods, including preventative and corrective actions, as well as root cause analyses to ascertain and rectify excess emissions. The EPA would also consider whether the source’s failure to comply with the CAA section 112(d) standard was, in fact, sudden, infrequent, not reasonably preventable and was not instead caused in part by poor maintenance or careless operation. 40 CFR 63.2 (definition of malfunction).

If the EPA determines in a particular case that an enforcement action against a source for violation of an emission standard is warranted, the source can raise any and all defenses in that enforcement action and the federal district court will determine what, if any, relief is appropriate. The same is true for citizen enforcement actions. Similarly, the presiding officer in an administrative proceeding can consider any defense raised and determine whether administrative penalties are appropriate.

In summary, the EPA interpretation of the CAA and, in particular, CAA section 112, is reasonable and encourages practices that will avoid malfunctions. Administrative and judicial procedures for addressing exceedances of the standards fully recognize that violations may occur despite good faith efforts to comply and can accommodate those situations. *U.S. Sugar Corporation v. EPA* (830 F.3d 579, 606–610; D.C. Cir. 2016).

a. General Duty

We are proposing to revise the General Provisions table (Table 8) entry

for 40 CFR 63.6(e)(1) by redesignating it as 40 CFR 63.6(e)(1)(i) and changing the “yes” in column 3 to a “no.” Section 63.6(e)(1)(i) describes the general duty to minimize emissions. Some of the language in that section is no longer necessary or appropriate in light of the elimination of the SSM exemption. We are proposing instead to add general duty regulatory text at 40 CFR 63.7100 that reflects the general duty to minimize emissions while eliminating the reference to periods covered by an SSM exemption. The current language in 40 CFR 63.6(e)(1)(i) characterizes what the general duty entails during periods of SSM. With the elimination of the SSM exemption, there is no need to differentiate between normal operations and SSM events in describing the general duty. Therefore, the language the EPA is proposing for 40 CFR 63.7100 does not include that language from 40 CFR 63.6(e)(1).

We are also proposing to revise Table 8 to add an entry for 40 CFR 63.6(e)(1)(ii) and include a “no” in column 3. Section 63.6(e)(1)(ii) imposes requirements that are not necessary with the elimination of the SSM exemption or are redundant with the general duty requirement being added at 40 CFR 63.7100.

We are also proposing to revise Table 8 to add an entry for 40 CFR 63.6(e)(1)(iii) and include a “yes” in column 3.

Finally, we are proposing to revise Table 8 to remove an entry for 40 CFR 63.6(e)(2) because this paragraph is reserved and is not applicable to 40 CFR part 63, subpart AAAAA.

b. SSM Plan

We are proposing to revise Table 8 for 40 CFR 63.6(e)(3) and include a “no” in column 3. Generally, these paragraphs require development of an SSM plan and specify SSM recordkeeping and reporting requirements related to the SSM plan. As noted, the EPA is proposing to remove the SSM exemptions. Therefore, affected units will be subject to an emission standard during such events. The applicability of a standard during such events will ensure that sources have ample incentive to plan for and achieve compliance and, thus, the SSM plan requirements are no longer necessary.

c. Compliance With Standards

We are proposing to revise Table 8 entry for 40 CFR 63.6(f)(1)–(3) by redesignating it as 40 CFR 63.6(f)(2)–(3) and adding an entry for 40 CFR 63.6(f)(1) and including a “no” in column 3. The current language of 40 CFR 63.6(f)(1) exempts sources from

non-opacity standards during periods of SSM. As discussed above, the Court in *Sierra Club* vacated the exemptions contained in this provision and held that the CAA requires that some CAA section 112 standards apply continuously. Consistent with *Sierra Club*, the EPA is proposing to revise standards in this rule to apply at all times.

We are proposing to revise Table 8 entry for 40 CFR 63.6(h)(1)–(2) by redesignating it as 40 CFR 63.6(h)(2) and adding an entry for 40 CFR 63.6(h)(1) and including a “no” in column 3. The current language of 40 CFR 63.6(h)(1) exempts sources from opacity standards during periods of SSM. As discussed above, the Court in *Sierra Club* vacated the exemptions contained in this provision and held that the CAA requires that some section 112 standards apply continuously. Consistent with *Sierra Club*, the EPA is proposing standards in this rule to apply at all times.

d. Performance Testing

We are proposing to revise Table 8 entry for 40 CFR 63.7(e)(1)–(4) by redesignating it as 40 CFR 63.7(e)(2)–(4) and adding an entry for 40 CFR 63.7(e)(1) and including a “no” in column 3. Section 63.7(e)(1) describes performance testing requirements. The EPA is instead proposing to revise the performance testing requirement at 40 CFR 63.7112 to remove the language “according to the requirements in § 63.7(e)(1)” because 40 CFR 63.7(e)(1) restated the SSM exemption. 40 CFR 63.7112(c) of the current rule specifies that performance testing must not be conducted during periods of SSM. Section 63.7112(b) also specifies that the performance test be conducted under the specific conditions specified in Table 4 to this subpart. Operations during periods of SSM, and during periods of nonoperation do not constitute representative operating conditions. The current language in 40 CFR 63.7112(h) requires the owner or operator to record the process information that is necessary to document operating conditions during the test and the EPA is proposing to add language that requires the owner and operator to include in such record an explanation to support that such conditions represent normal operation. Section 63.7(e) requires that the owner or operator make available to the Administrator such records “as may be necessary to determine the condition of the performance test” available to the Administrator upon request but does not specifically require the information to be recorded. The regulatory text in

the current rule already makes explicit the requirement to record the information.

e. Monitoring

We are proposing to revise Table 8 entry for 40 CFR 63.8(c)(1)–(3) by redesignating it as 40 CFR 63.8(c)(2)–(3) and adding entries for 40 CFR 63.8(c)(1)(i) and 40 CFR 63.8(c)(1)(iii) and including a “no” in column 3. The cross-references to the general duty and SSM plan requirements in those subparagraphs are not necessary considering other requirements of 40 CFR 63.8 that require good air pollution control practices (40 CFR 63.8(c)(1)) and that set out the requirements of a quality control program for monitoring equipment (40 CFR 63.8(d)).

f. Recordkeeping

We are proposing to revise the Table 8 entry for 40 CFR 63.10(b)(1)–(b)(2)(xii) by redesignating it as 40 CFR 63.10(b)(1) and adding an entry for 40 CFR 63.10(b)(2)(i) and including a “no” in column 3. Section 63.10(b)(2)(i) describes the recordkeeping requirements during startup and shutdown. We are instead proposing to add recordkeeping requirements to 40 CFR 63.7132. When a source is subject to a different standard during startup and shutdown, it will be important to know when such startup and shutdown periods begin and end in order to determine compliance with the appropriate standard. Thus, the EPA is proposing language in 40 CFR 63.7132 requiring that sources subject to an emission standard during startup or shutdown that differs from the emission standard that applies at all other times must report the date, time, and duration of such periods.

We are proposing to revise Table 8 to add an entry for 40 CFR 63.10(b)(2)(ii) and include a “no” in column 3. Section 63.10(b)(2)(ii) describes the recordkeeping requirements during a malfunction. A similar record is already required in 40 CFR 63.7131(d) and (e). The regulatory text in 40 CFR 63.7131(d) and (e) differs from the General Provisions in that the General Provisions requires the creation and retention of a record of the occurrence and duration of each malfunction of process, air pollution control, and monitoring equipment; whereas 40 CFR 63.7131(d) and (e) applies to any failure to meet an applicable standard and is requiring that the source record the date, time, and duration of the failure rather than the “occurrence.” The EPA is also proposing to add to 40 CFR 63.7132 a requirement that sources keep records that include a list of the affected

source or equipment and actions taken to minimize emissions, an estimate of the quantity of each regulated pollutant emitted over the standard for which the source failed to meet the standard, and a description of the method used to estimate the emissions. Examples of such methods would include product-loss calculations, mass balance calculations, measurements when available, or engineering judgment based on known process parameters. The EPA is proposing to require that sources keep records of this information to ensure that there is adequate information to allow the EPA to determine the severity of any failure to meet a standard, and to provide data that may document how the source met the general duty to minimize emissions when the source has failed to meet an applicable standard.

We are proposing to revise Table 8 by adding an entry for 40 CFR 63.10(b)(2)(iv) and including a “no” in column 3. When applicable, the provision requires sources to record actions taken during SSM events when actions were inconsistent with their SSM plan. The requirement is no longer appropriate because SSM plans will no longer be required. The requirement previously applicable under 40 CFR 63.10(b)(2)(iv)(B) to record actions to minimize emissions and record corrective actions is now applicable by reference to 40 CFR 63.7132.

We are proposing to revise Table 8 by adding an entry for 40 CFR 63.10(b)(2)(v) and including a “no” in column 3. When applicable, the provision requires sources to record actions taken during SSM events to show that actions taken were consistent with their SSM plan. The requirement is no longer appropriate because SSM plans will no longer be required.

g. Reporting

We are proposing to revise the Table 8 entry for 40 CFR 63.10(d)(5) by changing the “yes” in column 3 to a “no.” Section 63.10(d)(5) describes the reporting requirements for startups, shutdowns, and malfunctions. To replace the General Provisions reporting requirement, the EPA is proposing to add reporting requirements to 40 CFR 63.7131. The replacement language differs from the General Provisions requirement in that it eliminates periodic SSM reports as a stand-alone report. We are proposing language that requires sources that fail to meet an applicable standard at any time to report the information concerning such events in the semi-annual compliance report already required under this rule. We are proposing that the report must also

contain the number, date, time, duration, and the cause of such events (including unknown cause, if applicable), a list of the affected source or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to estimate the emissions.

Examples of such methods would include product-loss calculations, mass balance calculations, measurements when available, or engineering judgment based on known process parameters. The EPA is proposing this requirement to ensure that there is adequate information to determine compliance, to allow the EPA to determine the severity of the failure to meet an applicable standard, and to provide data that may document how the source met the general duty to minimize emissions during a failure to meet an applicable standard.

We will no longer require owners or operators to determine whether actions taken to correct a malfunction are consistent with an SSM plan, because plans would no longer be required. The proposed amendments, therefore, eliminate the cross-reference to 40 CFR 63.10(d)(5)(i) that contains the description of the previously required SSM report format and submittal schedule from this section. These specifications are no longer necessary because the events will be reported in otherwise required reports with similar format and submittal requirements. Section 63.10(d)(5)(ii) describes an immediate report for startups, shutdowns, and malfunctions when a source failed to meet an applicable standard but did not follow the SSM plan. We will no longer require owners and operators to report when actions taken during a startup, shutdown, or malfunction were not consistent with an SSM plan because plans would no longer be required.

2. Electronic Reporting Requirements

Through this proposal, the EPA is proposing that beginning 180 days after publication of the final rule in the **Federal Register**, owners and operators of lime manufacturing facilities submit electronic copies of required Notification of Compliance Status reports (portable document format (PDF), semiannual reports, and performance test reports through the EPA’s Central Data Exchange (CDX) using the Compliance and Emissions Data Reporting Interface (CEDRI). A description of the electronic data submission process is provided in the memorandum titled *Electronic Reporting Requirements for New Source*

Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules, available in Docket ID No. EPA–HQ–OAR–2017–0015. The proposed rule requires that performance test results collected using test methods that are supported by the EPA’s Electronic Reporting Tool (ERT) as listed on the ERT website²⁸ at the time of the test be submitted in the format generated through the use of the ERT, and that other performance test results be submitted in PDF using the attachment module of the ERT.

For compliance reports, the proposed rule requires that owners and operators use the appropriate spreadsheet template to submit information to CEDRI beginning 181 days after publication of the final rule in the **Federal Register**. A draft version of the proposed template for these reports is included in the docket for this rulemaking.²⁹ The EPA specifically requests comment on the content, layout, and overall design of the template.

Additionally, the EPA has identified two broad circumstances in which electronic reporting extensions may be provided. In both circumstances, the decision to accept the claim of needing additional time to report is within the discretion of the Administrator, and reporting should occur as soon as possible. The EPA is providing these potential extensions to protect owners and operators from noncompliance in cases where they cannot successfully submit a report by the reporting deadline for reasons outside of their control. The first situation in which an extension may be warranted is due to outages of the EPA’s CDX or CEDRI that precludes an owner or operator from accessing the system and submitting required reports is addressed in 40 CFR 63.8693(h). The second situation is due to a force majeure event, which is defined as an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents an owner or operator from complying with the requirement to submit a report electronically as required by this rule is addressed in 40 CFR 63.8693(i). Examples of such events are acts of nature, acts of war or terrorism, or

²⁸ <https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert>.

²⁹ See 40 CFR Part 63, Subpart AAAAA National Emission Standards for Hazardous Air Pollutants: Lime Manufacturing Plants Residual Risk and Technology Review, Semiannual Spreadsheet Template Draft.xlsm, available at Docket ID No. EPA–HQ–OAR–2017–0015.

equipment failure or safety hazards beyond the control of the facility.

The electronic submittal of the reports addressed in this proposed rulemaking will increase the usefulness of the data contained in those reports, is in keeping with current trends in data availability and transparency, will further assist in the protection of public health and the environment, will improve compliance by facilitating the ability of regulated facilities to demonstrate compliance with requirements, and by facilitating the ability of delegated state, local, tribal, and territorial air agencies and the EPA to assess and determine compliance, and will ultimately reduce burden on regulated facilities, delegated air agencies, and the EPA. Electronic reporting also eliminates paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors, and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the public. Moreover, electronic reporting is consistent with the EPA's plan³⁰ to implement Executive Order 13563 and is in keeping with the EPA's Agency-wide policy³¹ developed in response to the White House's Digital Government Strategy.³² For more information on the benefits of electronic reporting, see the memorandum titled *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules*, available in Docket ID No. EPA-HQ-OAR-2017-0015.

3. Technical and Editorial Changes

The following are additional proposed changes that address technical and editorial corrections:

- Revising the monitoring requirements in 40 CFR 63.7113 to the provision that triboelectric bag leak detection system must be installed, calibrated, operated, and maintained according to EPA-454/R-98-015. *Fabric Filter Bag Leak Detection Guidance*;
- Revising 40 CFR 63.7142 to add an alternative test method to EPA Method 320;

- Revising 40 CFR.7142 to add the latest version of ASTM Method D6735-01;
- Revising 40 CFR.7142 to add the latest version of ASTM Method D6420-99; and
- Revising Table 4 to 40 CFR part 63, subpart AAAAA, to add alternative compliance option.

E. What compliance dates are we proposing?

The EPA is proposing that existing affected sources must comply with the amendments in this rulemaking no later than 180 days after the effective date of the final rule. The EPA is also proposing that affected sources that commence construction or reconstruction after September 16, 2019 must comply with all requirements of the subpart, including the amendments being proposed, no later than the effective date of the final rule or upon startup, whichever is later. All affected existing facilities would have to continue to meet the current requirements of 40 CFR part 63, subpart AAAAA, until the applicable compliance date of the amended rule. The final action is not expected to be a "major rule" as defined by 5 U.S.C. 804(2), therefore, the effective date of the final rule will be the promulgation date as specified in CAA section 112(d)(10). For existing affected sources, we are proposing two changes that would impact ongoing compliance requirements for 40 CFR part 63, subpart AAAAA. As discussed elsewhere in this preamble, we are proposing to add a requirement that notifications, performance test results, and the semiannual reports using the new template be submitted electronically. We are also proposing to change the requirements for SSM by removing the exemption from the requirements to meet the standard during SSM periods and by removing the requirement to develop and implement an SSM plan. Our experience with similar industries that have been required to convert reporting mechanisms, install necessary hardware, become familiar with the process of submitting performance test results electronically through the EPA's CEDRI, test these new electronic submission capabilities, reliably employ electronic reporting, and convert logistics of reporting processes to different time-reporting parameters shows that a time period of a minimum of 90 days, and more typically, 180 days, is generally necessary to successfully complete these changes. Our experience with similar industries further shows that this sort of regulated facility generally requires a

time period of 180 days to read and understand the amended rule requirements; evaluate their operations to ensure that they can meet the standards during periods of startup and shutdown as defined in the rule and make any necessary adjustments; adjust parameter monitoring and recording systems to accommodate revisions; and update their operations to reflect the revised requirements. The EPA recognizes the confusion that multiple different compliance dates for individual requirements would create and the additional burden such an assortment of dates would impose. From our assessment of the time frame needed for compliance with the entirety of the revised requirements, the EPA considers a period of 180 days to be the most expeditious compliance period practicable, and, thus, is proposing that existing affected sources be in compliance with all of this regulation's revised requirements within 180 days of the regulation's effective date. We solicit comment on this proposed compliance period, and we specifically request submission of information from sources in this source category regarding specific actions that would need to be undertaken to comply with the proposed amended requirements and the time needed to make the adjustments for compliance with any of the revised requirements. We note that information provided may result in changes to the proposed compliance date.

V. Summary of Cost, Environmental, and Economic Impacts

A. What are the affected sources?

There are currently 35 lime manufacturing facilities operating in the United States that are subject to the Lime Manufacturing Plants NESHAP. The 40 CFR part 63, subpart AAAAA, affected source is the lime kiln and its associated cooler, and the PSH operation system located at a major source of HAP emissions. A new or reconstructed affected source is a source that commenced construction after December 20, 2002, or meets the definition of reconstruction and commenced reconstruction after December 20, 2002.

B. What are the air quality impacts?

At the current level of control, emissions of total HAP are estimated to be approximately 2,320 tpy in 2019. This represents a reduction in HAP emissions of about 240 tpy due to the current (2004) Lime Manufacturing Plants NESHAP. The proposed amendments will require all affected

³⁰ The EPA's *Final Plan for Periodic Retrospective Reviews*, August 2011. Available at: <https://www.regulations.gov/documentD=EPA-HQ-OA-2011-0156-0154>.

³¹ *E-Reporting Policy Statement for EPA Regulations*, September 2013. Available at: <https://www.epa.gov/sites/production/files/2016-03/documents/epa-ereporting-policy-statement-2013-09-30.pdf>.

³² *Digital Government: Building a 21st Century Platform to Better Serve the American People*, May 2012. Available at: <https://obamawhitehouse.archives.gov/sites/default/files/omb/egov/digital-government/digital-government.html>.

sources subject to the emission standards in the Lime Manufacturing Plants NESHAP to operate without the SSM exemption. We were unable to quantify the specific emissions reduction associated with eliminating the SSM exemption. However, eliminating the SSM exemption will reduce emissions by requiring facilities to meet the proposed work practice standards during SSM periods.

Indirect or secondary air emissions impacts are impacts that would result from the increased electricity usage associated with the operation of control devices (*i.e.*, increased secondary emissions of criteria pollutants from power plants). Energy impacts consist of the electricity and steam needed to operate control devices and other equipment that would be required under this proposed rule. The EPA expects no secondary air emissions impacts or energy impacts from this rulemaking.

C. What are the cost impacts?

The 35 lime manufacturing plants that would be subject to the proposed amendments would incur minimal net costs to meet revised recordkeeping and reporting requirements and the proposed work practice standards for periods of startup and shutdown. Nationwide costs associated with the proposed requirements are estimated to be \$14,355 following promulgation of the amendments. The EPA believes that the lime manufacturing plants which are subject to the NESHAP can meet the proposed requirements with minimal additional capital or operational costs. For further information on the requirements being proposed, see section IV of this preamble. Each facility will experience costs to read and understand the rule amendments. Costs associated with the elimination of the SSM exemption were estimated as part of the reporting and recordkeeping costs and include time for re-evaluating previously developed SSM record systems. Costs associated with the requirement to electronically submit notifications and semi-annual compliance reports using CEDRI were estimated as part of the reporting and recordkeeping costs and include time for becoming familiar with CEDRI and the reporting template for semi-annual compliance reports. We solicit comment on these estimated cost impacts.

D. What are the economic impacts?

Economic impact analyses focus on changes in market prices and output levels. If changes in market prices and output levels in the primary markets are significant enough, impacts on other

markets may also be examined. Both the magnitude of costs needed to comply with a proposed rule and the distribution of these costs among affected facilities can have a role in determining how the market will change in response to a proposed rule. The total costs associated with reviewing the final rule, meeting the revised recordkeeping and reporting requirements, and complying with the proposed work practice standards are estimated to be \$14,355 following promulgation of the final rule. This is an estimated cost of \$250 to \$2750 per facility, depending on the number of lime kilns operated and the type of controls installed. These costs are not expected to result in a significant market impact, regardless of whether they are passed on to the purchaser or absorbed by the firms. Based on the costs associated with the elimination of the SSM exemption and the costs associated with the requirement to electronically submit compliance reports, we do not anticipate any significant economic impacts from these proposed amendments.

E. What are the benefits?

Although the EPA does not anticipate reductions in HAP emissions as a result of the proposed amendments, we believe that the action, if finalized as proposed, would result in improvements to the rule. Specifically, the proposed amendments revise the standards such that they apply at all times. For facilities who choose to operate under an initial startup period, the EPA is proposing an alternative work practice standard that will ensure that facilities are minimizing emissions while the source operates under non-steady state production, which will protect public health and the environment. Additionally, the proposed amendments requiring electronic submittal of initial notifications, initial startup reports, annual compliance certifications, deviation reports, and performance test results will increase the usefulness of the data, is in keeping with current trends of data availability, will further assist in the protection of public health and the environment, and will ultimately result in less burden on the regulated community. See section IV.D.2 of this preamble for more information.

VI. Request for Comments

We solicit comments on all aspects of this proposed action. In addition to general comments on this proposed action, we are also interested in additional data that may improve the

risk assessments and other analyses. We are specifically interested in receiving any improvements to the data used in the site-specific emissions profiles used for risk modeling. Such data should include supporting documentation in sufficient detail to allow characterization of the quality and representativeness of the data or information. Section VII of this preamble provides more information on submitting data.

VII. Submitting Data Corrections

The site-specific emissions profiles used in the source category risk and demographic analyses and instructions are available for download on the RTR website at <https://www.epa.gov/stationary-sources-air-pollution/lime-manufacturing-plants-national-emission-standards-hazardous-air>. The data files include detailed information for each HAP emissions release point for the facilities in the source category.

If you believe that the data are not representative or are inaccurate, please identify the data in question, provide your reason for concern, and provide any “improved” data that you have, if available. When you submit data, we request that you provide documentation of the basis for the revised values to support your suggested changes. To submit comments on the data downloaded from the RTR website, complete the following steps:

1. Within this downloaded file, enter suggested revisions to the data fields appropriate for that information.
2. Fill in the commenter information fields for each suggested revision (*i.e.*, commenter name, commenter organization, commenter email address, commenter phone number, and revision comments).
3. Gather documentation for any suggested emissions revisions (*e.g.*, performance test reports, material balance calculations).
4. Send the entire downloaded file with suggested revisions in Microsoft® Access format and all accompanying documentation to Docket ID No. EPA-HQ-OAR-2017-0015 (through the method described in the **ADDRESSES** section of this preamble).

5. If you are providing comments on a single facility or multiple facilities, you need only submit one file for all facilities. The file should contain all suggested changes for all sources at that facility (or facilities). We request that all data revision comments be submitted in the form of updated Microsoft® Excel files that are generated by the Microsoft® Access file. These files are provided on the RTR website at <https://www.epa.gov/stationary-sources-air>

pollution/lime-manufacturing-plants-national-emission-standards-hazardous-air.

VIII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was, therefore, not submitted to OMB for review.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not expected to be an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to OMB under the PRA. The ICR document that the EPA prepared has been assigned EPA ICR number 2072.06. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

We are proposing changes to the reporting and recordkeeping requirements for the Lime Manufacturing Plants NESHAP in the form of eliminating the SSM reporting and SSM plan requirements and requiring electronic submittal of all compliance reports (including performance test reports). Any information submitted to the Agency for which a claim of confidentiality is made will be safeguarded according to the Agency policies set forth in title 40, chapter 1, part 2, subpart B—Confidentiality of Business Information (see 40 CFR 2; 41 FR 36902, September 1, 1976; amended by 43 FR 40000, September 8, 1978; 43 FR 42251, September 20, 1978; 44 FR 17674, March 23, 1979).

Respondents/affected entities: Owners and operators of lime manufacturing plants that are major sources, or that are located at, or are part of, major sources of HAP emissions, unless the lime manufacturing plant is located at a kraft pulp mill, soda pulp mill, sulfite pulp mill, sugar beet manufacturing plant, or only processes sludge containing calcium carbonate from water softening processes.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart AAAAA).

Estimated number of respondents: On average over the next 3 years, approximately 36 existing major sources will be subject to these standards. It is also estimated that one additional respondent will become subject to the emission standards over the 3-year period.

Frequency of response: The frequency of responses varies depending on the burden item.

Total estimated burden: The average annual burden to industry over the next 3 years from these recordkeeping and reporting requirements is estimated to be 9,690 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost of entire rule: The annual recordkeeping and reporting cost for all facilities to comply with all of the requirements in the NESHAP is estimated to be \$1,400,000 (per year), of which \$14,355 (first year) is for this proposal, and the rest is for other costs related to continued compliance with the NESHAP including \$338,000 in annualized capital and operation and maintenance costs.

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 the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to OIRA_submission@omb.eop.gov, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than October 16, 2019. The EPA will respond to any ICR-related comments in the final rule.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. This action only proposes to eliminate the startup/shutdown exemption and add electronic reporting. Neither of the changes being proposed will impact the small entities.

The proposal to remove the startup/shutdown exemption will include proposing a work practice standard for those periods. Based on the controls used at the small entities, they will not be impacted by the proposed work practices. Thus, this action will not impose any requirements on small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. The EPA does not know of any lime manufacturing facilities owned or operated by Indian tribal governments. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in sections III and IV of this preamble and further documented in the risk report titled *Residual Risk Assessment for the Lime Manufacturing Source Category in Support of the 2019 Risk and Technology Review Proposed Rule*, which is available in the docket for this action.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a

significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This action involves technical standards. The EPA proposes to use ANSI/ASME PTC 19.10–1981 Part 10 (2010), “Flue and Exhaust Gas Analyses,” as an acceptable alternative to EPA Method 3B manual portion only and not the instrumental portion. This method determines quantitatively the gaseous constituents of exhausts resulting from stationary combustion sources. This standard may be obtained from <https://www.asme.org> or from the American Society of Mechanical Engineers (ASME) at Three Park Avenue, New York, New York 10016–5990.

The EPA proposes to use ASTM D6348–12e1, Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy,” as an alternative to using EPA Method 320 under certain conditions and incorporate this alternative by reference. ASTM D6348–03(2010) was previously determined equivalent to EPA Method 320 with caveats. ASTM D6348–12e1 is a revised version of ASTM D6348–03(2010) and includes a new section on accepting the results from direct measurement of a certified spike gas cylinder, but still lacks the caveats we placed on the ASTM D6348–03(2010) version. The voluntary consensus standard (VCS), ASTM D6348–12e1, “Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy,” is an acceptable alternative to EPA Method 320 at this time with caveats requiring inclusion of selected annexes to the standard as mandatory. When using ASTM D6348–12e1, the conditions that must be met are defined in 40 CFR 63.7142(a)(2). This field test method employs an extractive sampling system to direct stationary source effluent to an FTIR spectrometer for the identification and quantification of gaseous compounds. The ASTM D6348–12e1 standard was developed and adopted by the American Society for Testing and Materials (ASTM).

The EPA also proposes to use ASTM D6735–01 (Reapproved 2009), “Standard Test Method for Measurement of Gaseous Chlorides and Fluorides from Mineral Calcining Exhaust Sources Impinger Method,” as an alternative to EPA Method 321 provided that the provisions in 40 CFR 63.7142(a)(4) are followed. The EPA used ASTM D6735–01 for the

determination of HCl in EPA Methods 26, 26A, and 321 from mineral calcining exhaust sources. This method will measure the gaseous hydrochloric acid and other gaseous chlorides and fluorides that passes through a particulate matter filter. The ASTM D6735–01 standard was developed and adopted by the ASTM.

The EPA proposes to use VCS ASTM D6420–99 (Reapproved 2010), “Test Method for Determination of Gaseous Organic Compounds by Direct Interface Gas Chromatography/Mass Spectrometry” as an alternative to EPA Method 18 only when the target compounds are all known, and the target compounds are all listed in ASTM D6420 as measurable. ASTM D6420 should not be used for methane and ethane because atomic mass is less than 35. ASTM D6420 should never be specified as a total VOC method. This field method determines the mass concentration of volatile organic hazardous air pollutants.

The ASTM standards may be obtained from <http://www.astm.org> or from the ASTM at 100 Barr Harbor Drive, Post Office C700, West Conshohocken, Pennsylvania 19428–2959.

The EPA proposes to use EPA–454/R–98–015, Office of Air Quality Planning and Standards (OAQPS), Fabric Filter Bag Leak Detection Guidance, September 1997 as guidance for how a triboelectric bag leak detection system must be installed, calibrated, operated, and maintained. This document includes fabric filter and monitoring system descriptions; guidance on monitor selection, installation, set up, adjustment, and operation; and quality assurance procedures. This document may be obtained from <http://www.epa.gov> or from the U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

While the EPA has identified another 10 VCS as being potentially applicable to this proposed rule, we have decided not to use these VCS in this rulemaking. The use of these VCS would not be practical due to lack of equivalency, documentation, validation data, and other import technical and policy considerations. See the memorandum titled *Voluntary Consensus Standard Results for NESHAP: Lime Manufacturing Residual Risk and Technology Review*, in the docket for this proposed rule for the reasons for these determinations.

Under 40 CFR 63.7(f) and 40 CFR 63.8(f) of subpart A of the General Provisions, a source may apply to the EPA for permission to use alternative test methods or alternative monitoring

requirements in place of any required testing methods, performance specifications, or procedures in the final rule or any amendments.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

The documentation for this decision is contained in section IV.B of this preamble and the technical report, *Risk and Technology Review Analysis of Demographic Factors for Populations Living Near Lime Manufacturing Source Category Operations*, which is available in the docket for this action.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Incorporation by reference, Lime kilns, Lime manufacturing, Reporting and recordkeeping requirements.

Dated: August 19, 2019.

Andrew R. Wheeler,
Administrator.

For the reasons stated in the preamble, 40 CFR part 63 is proposed to be amended as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continuous to read as follows:

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

Subpart A—General Provisions

■ 2. Section 63.14 is amended by adding paragraph (e)(2), and revising paragraphs (h)(85), (h)(91), (h)(96), and (n)(3) to read as follows:

§ 63.14 Incorporation by reference.

* * * * *

(e) * * *

(2) ANSI/ASME PTC 19.10–1981 (2010), Flue and Exhaust Gas Analyses (Part 10, Instruments and Apparatus), re-issued 2010, IBR approved for table 4 to subpart AAAAA.

* * * * *

(h) * * *

(85) ASTM D6348–12e1, Standard Test Method for Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform

Infrared (FTIR) Spectroscopy, Approved February 1, 2012, IBR approved for §§ 63.1571(a) and 63.7142(a) and (b).

* * * * *

(91) ASTM D6420–99 (Reapproved 2010), Standard Test Method for Determination of Gaseous Organic Compounds by Direct Interface Gas Chromatography-Mass Spectrometry, Approved October 1, 2010, IBR approved for §§ 63.670(j), 63.7142(b), and appendix A to this part: Method 325B.

* * * * *

(96) ASTM D6735–01 (Reapproved 2009), Standard Test Method for Measurement of Gaseous Chlorides and Fluorides from Mineral Calcining Exhaust Sources—Impinger Method, IBR approved for § 63.7142(a), tables 4 and 5 to subpart JJJJ, and tables 4 and 6 to subpart KKKKK.

* * * * *

(n) * * *

(3) EPA–454/R–98–015, Office of Air Quality Planning and Standards (OAQPS), Fabric Filter Bag Leak Detection Guidance, September 1997, <https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=2000D5T6.PDF>, IBR approved for §§ 63.548(e), 63.864(e), 63.7113(d), 63.7525(j), 63.8450(e), 63.8600(e), and 63.11224(f).

Subpart AAAAA—[Amended]

■ 3. Section 63.7083 is amended by revising paragraphs (a)(1), (a)(2), and (b) and adding paragraph (e) to read as follows:

§ 63.7083 When do I have to comply with this subpart?

(a) * * *

(1) If you start up your affected source before January 5, 2004, you must comply with the emission limitations no later than January 5, 2004, and you must have completed all applicable performance tests no later than July 5, 2004, except as noted in paragraphs (e)(1) and (2) of this section.

(2) If you start up your affected source after January 5, 2004, then you must comply with the emission limitations for new affected sources upon startup of your affected source and you must have completed all applicable performance tests no later than 180 days after startup, except as noted in paragraphs (e)(1) and (2) of this section.

(b) If you have an existing affected source, you must comply with the applicable emission limitations for the existing affected source, and you must have completed all applicable performance tests no later than January

5, 2007, except as noted in paragraphs (e)(1) and (2) of this section.

* * * * *

(e)(1) If the start up of your existing, new, or reconstructed source occurs on or before [DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], then the compliance date for the revised requirements promulgated at §§ 63.7090, 63.7100, 63.7112, 63.7113, 63.7121, 63.7131, 63.7132, 63.7140, 63.7141, 63.7142, and 63.7143 and Tables 1, 2, 3, 4, 6, 7, and 8 of 40 CFR 63, subpart AAAAA, published on [DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**] for both new and existing sources is [DATE 180 DAYS AFTER THE DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**].

(2) If the initial start up of your new or reconstructed source occurs after [DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], then the compliance date for the revised requirements promulgated at §§ 63.7090, 63.7100, 63.7112, 63.7113, 63.7121, 63.7131, 63.7132, 63.7140, 63.7141, 63.7142, and 63.7143 and Tables 1, 2, 3, 4, 6, 7, and 8 of 40 CFR 63, subpart AAAAA, published on [DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**] is [DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**] or the date of startup, whichever is later.

■ 4. Section 63.7090 is amended by adding paragraph (c) to read as follows:

§ 63.7090 What emission limitations must I meet?

* * * * *

(c) After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], during periods of startup and shutdown you must meet the requirements listed in paragraphs (c)(1) through (6) of this section.

(1) During startup you must fire your kiln with any one or combination of the following clean fuels: natural gas, synthetic natural gas, propane, distillate oil, synthesis gas (syngas), or ultra-low sulfur diesel (ULSD) until the kiln reaches a temperature of 1200 degrees Fahrenheit.

(2) Combustion of the primary kiln fuel may commence once the kiln temperature reaches 1200 degrees Fahrenheit.

(3) Kilns and coolers (if there is a separate exhaust to the atmosphere from the associated lime cooler) equipped with a fabric filter (FF) must comply with the opacity operating limit in Table 2 in lieu of the particulate (PM) emission limits.

(4) Kilns and coolers (if there is a separate exhaust to the atmosphere from the associated lime cooler) equipped with a wet scrubber must meet the scrubber liquid flow rate operating limit in Table 2 in lieu of the PM emission limits.

(5) For kilns and coolers (if there is a separate exhaust to the atmosphere from the associated lime cooler) equipped with an electrostatic precipitator (ESP), the ESP must be turned on and operating at the time the gas stream at the inlet to the ESP reaches 300 degrees Fahrenheit (five-minute average) during startup. Temperature of the gas stream is to be measured at the inlet of the ESP every minute.

(6) You must keep records as specified in § 63.7132 during periods of startup and shutdown.

■ 5. Section 63.7100 is amended by revising paragraphs (a), (b), (c), (d)(3), (d)(4)(iii), and (e) to read as follows:

§ 63.7100 What are my general requirements for complying with this subpart?

(a) Prior to [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], you must be in compliance with the emission limitations (including operating limits) in this subpart at all times, except during periods of startup, shutdown, and malfunction. After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], you must be in compliance with the applicable emission limitations (including operating limits and work practices) at all times.

(b) Prior to [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], you must be in compliance with the opacity and visible emission (VE) limits in this subpart at all times, except during periods of startup, shutdown, and malfunction. After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], you must be in compliance with the applicable opacity and VE limits (including work practices) at all times.

(c) Prior to [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], you must always operate and maintain your affected source, including air pollution control and monitoring equipment, according to the provisions in § 63.6(e)(1)(i). After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], you must always operate and maintain any affected source, including associated air pollution control

equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require the owner or operator to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether such operation and maintenance procedures are being used will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.

(d) * * *

(3) Procedures for the proper operation and maintenance of each emission unit and each air pollution control device used to meet the applicable emission limitations and operating limits in Tables 1 and 2 to this subpart, respectively. After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], your OM&M plan must address periods of startup and shutdown.

(4) * * *

(iii) Prior to [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], ongoing operation and maintenance procedures in accordance with the general requirements of § 63.8(c)(1)(i) and (ii), (3), and (4)(ii). After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], ongoing operation and maintenance procedures in accordance with the general requirements of paragraph (c) of this section and §§ 63.8(c)(1)(ii), (3), and (4)(ii); and

* * * * *

(e) For affected sources until [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], you must develop a written startup, shutdown, and malfunction plan (SSMP) according to the provisions in § 63.6(e)(3).

■ 6. Section 63.7112 is amended by revising paragraphs (b), (c), (k)(3), paragraph (l) introductory text, and adding paragraph (m).

§ 63.7112 What performance tests, design evaluations, and other procedures must I use?

* * * * *

(b) Prior to [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], each performance test must be conducted according to the requirements in

§ 63.7(e)(1) and under the specific conditions specified in Table 4 to this subpart. After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], each performance test must be conducted based on representative performance (i.e., performance based on normal operating conditions) of the affected source and under the specific conditions in Table 4 to this subpart. Representative conditions exclude periods of startup and shutdown. The owner or operator may not conduct performance tests during periods of malfunction. The owner or operator must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, the owner or operator shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

(c) Prior to [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], you may not conduct performance tests during periods of startup, shutdown, or malfunction, as specified in § 63.7(e)(1). After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], during startup and shutdown, you must follow the requirements in § 63.7090(c).

* * * * *

(k) * * *

(3) The observer conducting the VE checks need not be certified to conduct EPA Method 9 in appendix A–4 to part 60 of this chapter, but must meet the training requirements as described in EPA Method 22 in appendix A–7 to part 60 of this chapter.

(l) When determining compliance with the opacity standards for fugitive emissions from PSH operations in item 8 of Table 1 to this subpart, you must conduct EPA Method 9 in appendix A–4 to part 60 of this chapter according to item 17 in Table 4 to this subpart, and in accordance with paragraphs (l)(1) through (3) of this section.

* * * * *

(m) After to [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], for kilns and coolers equipped with an ESP, the run average temperature must be calculated for each run, and the average of the run average temperatures must be determined and included in the performance test report and will be used to determine compliance with § 63.7090(c)(5).

■ 7. Section 63.7113 is amended by:

- a. Revising the introductory text to paragraph (d);
- b. Redesignating paragraphs (d)(3) through (8) as paragraphs (d)(4) through (9);
- c. Adding new paragraph (d)(3);
- d. Revising newly redesignated paragraph (d)(7), the introductory text to newly redesignated paragraph (d)(8), and newly redesignated paragraph (d)(9); and
- e. Adding paragraphs (d)(10) and (h).

The revisions and additions read as follows:

§ 63.7113 What are my monitoring installation, operation, and maintenance requirements?

* * * * *

(d) For each bag leak detection system (BLDS), you must meet any applicable requirements in paragraphs (a)(1) through (5) and (d)(1) through (9) of this section.

* * * * *

(3) The BLDS must be equipped with a device to continuously record the output signal from the sensor.

* * * * *

(7) Each triboelectric BLDS must be installed, calibrated, operated, and maintained according to EPA–454/R–98–015, “Fabric Filter Bag Leak Detection Guidance,” (incorporated by reference, see § 63.14). Other types of bag leak detection systems must be installed, operated, calibrated, and maintained according to the manufacturer’s written specifications and recommendations. Standard operating procedures must be incorporated into the OM&M plan.

(8) At a minimum, initial adjustment of the system must consist of establishing the baseline output in both of the following ways, according to section 5.0 of the EPA–454/R–98–015, “Fabric Filter Bag Leak Detection Guidance,” (incorporated by reference, see § 63.14):

* * * * *

(9) After initial adjustment, the sensitivity or range, averaging period, alarm set points, or alarm delay time may not be adjusted except as specified in the OM&M plan required by § 63.7100(d). In no event may the range be increased by more than 100 percent or decreased by more than 50 percent over a 365-day period unless such adjustment follows a complete FF inspection that demonstrates that the FF is in good operating condition, as defined in section 5.2 of the EPA–454/R–98–015, “Fabric Filter Bag Leak Detection Guidance,” (incorporated by reference, see § 63.14). Record each adjustment.

(10) Record the results of each inspection, calibration, and validation check.

* * * * *

(h) After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], for kilns and coolers equipped with an ESP, you must demonstrate compliance with the startup requirements in § 63.7090(c)(5) by meeting the requirements of paragraphs (h)(1) through (5) of this section.

(1) You must install, calibrate, maintain, and continuously operate a CMS to record the temperature of the exhaust gases at the inlet to, or upstream of, the ESP.

(2) The temperature recorder response range must include zero and 1.5 times the average temperature established during your performance test according to the requirements in § 63.7112(m).

(3) The calibration reference for the temperature measurement must be a National Institute of Standards and Technology calibrated reference thermocouple-potentiometer system or alternate reference, subject to approval by the Administrator.

(4) The calibration of all thermocouples and other temperature sensors must be verified at least once every three months.

(5) You must monitor and continuously record the temperature of the exhaust gases from the kiln and cooler, if applicable, at the inlet to the kiln and/or cooler ESP.

■ 8. Section 63.7121 is amended by revising paragraphs (b) and (d) to read as follows:

§ 63.7121 How do I demonstrate continuous compliance with the emission limitations standard?

* * * * *

(b) You must report each instance in which you did not meet each operating limit, work practice, opacity limit, and VE limit in Tables 2 and 6 to this subpart that applies to you. This includes periods of startup, shutdown, and malfunction. These instances are deviations from the emission limitations in this subpart. These deviations must be reported according to the requirements in § 63.7131.

* * * * *

(d) Prior to [DATE 181 DAYS AFTER THE DATE OF PUBLICATION OF FINAL RULE IN **Federal Register**], consistent with §§ 63.6(e) and 63.7(e)(1), deviations that occur during a period of startup, shutdown, or malfunction are not violations if you demonstrate to the Administrator's satisfaction that you were operating in accordance with § 63.6(e)(1). The Administrator will

determine whether deviations that occur during a period of startup, shutdown, or malfunction are violations, according to the provisions in § 63.6(e).

* * * * *

■ 9. Section 63.7130 is amended by revising paragraph (e) introductory text to read as follows:

§ 63.7130 What notifications must I submit and when?

* * * * *

(e) If you are required to conduct a performance test, design evaluation, opacity observation, VE observation, or other initial compliance demonstration as specified in Table 3 or 4 to this subpart, you must submit a Notification of Compliance Status according to § 63.9(h)(2)(ii). Beginning on [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], submit all subsequent Notification of Compliance Status following the procedure specified in § 63.7131(h).

* * * * *

■ 10. Section 63.7131 is amended by:

■ a. Revising paragraph (b) introductory text.

■ b. Adding paragraph (b)(6).

■ c. Revising paragraphs (c)(4) through (c)(6).

■ d. Revising paragraphs (d), (e) introductory text, and (e)(2).

■ e. Adding paragraph (e)(12)

■ f. Revising paragraph (f).

■ g. Adding paragraphs (g) through (j).

The revisions and additions read as follows:

§ 63.7131 What reports must I submit and when?

* * * * *

(b) Unless the Administrator has approved a different schedule for submission of reports under § 63.10(a), you must submit each report by the date specified in Table 7 to this subpart and according to the requirements in paragraphs (b)(1) through (6) of this section:

* * * * *

(6) Beginning on [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], submit all subsequent compliance reports following the procedure specified in paragraph (h) of this section.

(c) * * *

(4) Prior to [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], if you had a startup, shutdown, or malfunction during the reporting period and you took actions consistent with your SSMP, the compliance report must include the information in § 63.10(d)(5)(i).

(5) If there were no deviations from any emission limitations (emission limit, operating limit, work practice, opacity limit, and VE limit) that apply to you, the compliance report must include a statement that there were no deviations from the emission limitations during the reporting period.

(6) If there were no periods during which the continuous monitoring systems (CMS), including CPMS, were out-of-control as specified in § 63.8(c)(7), a statement that there were no periods during which the CMS were out-of-control during the reporting period.

(d) For each deviation from an emission limitation (emission limit, operating limit, work practice, opacity limit, and VE limit) that occurs at an affected source where you are not using a CMS to comply with the emission limitations in this subpart, the compliance report must contain the information specified in paragraphs (c)(1) through (4) and (d)(1) and (2) of this section. The deviations must be reported in accordance with the requirements in § 63.10(d) prior to [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**] and the requirements in § 63.10(d)(1)–(4) after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**].

(1) The total operating time of each emission unit during the reporting period.

(2) Information on the number, duration, and cause of deviations (including unknown cause, if applicable), and the corrective action taken.

(3) An estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to estimate the emissions.

(e) For each deviation from an emission limitation (emission limit, operating limit, work practice, opacity limit, and VE limit) occurring at an affected source where you are using a CMS to comply with the emission limitation in this subpart, you must include the information specified in paragraphs (c)(1) through (4) and (e)(1) through (11) of this section, except that after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**] the semiannual compliance report must also include the information included in paragraph (e)(12) of this section. This includes periods of startup, shutdown, and malfunction.

* * * * *

(2) The date, time, and duration that each CMS was inoperative, except for zero (low-level) and high-level checks.

* * * * *

(12) An estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to estimate the emissions.

(f) Each facility that has obtained a title V operating permit pursuant to part 70 or part 71 of this chapter must report all deviations as defined in this subpart in the semiannual monitoring report required by §§ 70.6(a)(3)(iii)(A) or 71.6(a)(3)(iii)(A) of this chapter. If you submit a compliance report specified in Table 7 to this subpart along with, or as part of, the semiannual monitoring report required by §§ 70.6(a)(3)(iii)(A) or 71.6(a)(3)(iii)(A) of this chapter, and the compliance report includes all required information concerning deviations from any emission limitation (including any operating limit and work practice), submission of the compliance report shall be deemed to satisfy any obligation to report the same deviations in the semiannual monitoring report. However, submission of a compliance report shall not otherwise affect any obligation you may have to report deviations from permit requirements to the permit authority.

(g) If you are required to submit reports following the procedure specified in this paragraph, you must submit reports to the EPA via the Compliance and Emissions Data Reporting Interface (CEDRI), which can be accessed through the EPA's Central Data Exchange (CDX) (<https://cdx.epa.gov/>). You must use the appropriate electronic report template on the CEDRI website (<https://www.epa.gov/electronic-reporting-air-emissions/compliance-and-emissions-data-reporting-interface-cedri>) for this subpart. The date report templates become available will be listed on the CEDRI website. The report must be submitted by the deadline specified in this subpart, regardless of the method in which the report is submitted. If you claim some of the information required to be submitted via CEDRI is confidential business information (CBI), submit a complete report, including information claimed to be CBI, to the EPA. The report must be generated using the appropriate form on the CEDRI website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement

Policy Group, MD C404-02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph.

(h) *Performance Tests.* Within 60 days after the date of completing each performance test required by this subpart, you must submit the results of the performance test following the procedures specified in paragraphs (h)(1) through (3) of this section.

(1) *Data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT website* (<https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert>) *at the time of the test.* Submit the results of the performance test to the EPA via CEDRI, which can be accessed through the EPA's CDX (<https://cdx.epa.gov/>). The data must be submitted in a file format generated through the use of the EPA's ERT. Alternatively, you may submit an electronic file consistent with the extensible markup language (XML) schema listed on the EPA's ERT website.

(2) *Data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the test.* The results of the performance test must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the ERT generated package or alternative file to the EPA via CEDRI.

(3) *Confidential business information (CBI).* If you claim some of the information submitted under paragraph (i) of this section is CBI, you must submit a complete file, including information claimed to be CBI, to the EPA. The file must be generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404-02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described in paragraph (i) of this section.

(i) If you are required to electronically submit a report or notification through CEDRI in the EPA's CDX, you may assert a claim of EPA system outage for failure to timely comply with the reporting requirement. To assert a claim of EPA system outage, you must meet

the requirements outlined in paragraphs (i)(1) through (7) of this section.

(1) You must have been or will be precluded from accessing CEDRI and submitting a required report within the time prescribed due to an outage of either the EPA's CEDRI or CDX systems.

(2) The outage must have occurred within the period of time beginning five business days prior to the date that the submission is due.

(3) The outage may be planned or unplanned.

(4) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(5) You must provide to the Administrator a written description identifying:

(i) The date(s) and time(s) when CDX or CEDRI was accessed and the system was unavailable;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to EPA system outage;

(iii) Measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(6) The decision to accept the claim of EPA system outage and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(7) In any circumstance, the report must be submitted electronically as soon as possible after the outage is resolved.

(j) *Claims of force majeure.* If you are required to electronically submit a report through CEDRI in the EPA's CDX, you may assert a claim of force majeure for failure to timely comply with the reporting requirement. To assert a claim of force majeure, you must meet the requirements outlined in paragraphs (j)(1) through (5) of this section.

(1) You may submit a claim if a force majeure event is about to occur, occurs, or has occurred or there are lingering effects from such an event within the period of time beginning five business days prior to the date the submission is due. For the purposes of this section, a force majeure event is defined as an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents you from complying with the requirement to submit a report electronically within the time period prescribed. Examples of such events are acts of nature (e.g., hurricanes,

earthquakes, or floods), acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility (e.g., large scale power outage).

(2) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(3) You must provide to the Administrator:

(i) A written description of the force majeure event;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to the force majeure event;

(iii) Measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(4) The decision to accept the claim of force majeure and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(5) In any circumstance, the reporting must occur as soon as possible after the force majeure event occurs.

■ 11. Section 63.7132 is amended by revising paragraph (a)(2) to read as follows:

§ 63.7132 What records must I keep?

(a) * * *

(2) Prior to [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], the records in § 63.6(e)(3)(iii) through (v) related to startup, shutdown, and malfunction. After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**], the records in paragraphs (a)(2)(i) through (iii) of this section.

(i) You must keep records of the date, time and duration of each startup and/or shutdown period for any affected source that is subject to a standard during startup or shutdown that differs from the standard applicable at other times.

(ii) You must keep records of the date, time, cause and duration of each malfunction that causes an affected source to fail to meet an applicable standard; if there was also a monitoring malfunction, the date, time, cause, and duration of the monitoring malfunction; the record must list the affected source or equipment, an estimate of the volume of each regulated pollutant emitted over the standard for which the source failed to meet a standard, and a description of the method used to estimate the emissions.

(iii) For kilns and coolers equipped with an ESP, the average of the run average temperatures determined in accordance with § 63.7112(m) must be recorded.

* * * * *

■ 12. Section 63.7133 is amended by adding paragraph (d) to read as follows:

§ 63.7133 In what form and for how long must I keep my records?

* * * * *

(d) Any records required to be maintained by this part that are submitted electronically via the EPA's CEDRI may be maintained in electronic format. This ability to maintain electronic copies does not affect the requirement for facilities to make records, data, and reports available upon request to a delegated air agency or the EPA as part of an on-site compliance evaluation.

■ 13. Section 63.7140 is revised to read as follows:

§ 63.7140 What parts of the General Provisions apply to me?

Table 8 to this subpart shows which parts of the General Provisions in §§ 63.1 through 63.16 apply to you. When there is overlap between 40 CFR part 63, subpart A, and 40 CFR part 63, subpart AAAAA, as indicated in the "Explanations" column in Table 8, 40 CFR part 63, subpart AAAAA takes precedence.

■ 14. Section 63.7141 is amended by:

■ a. Revising paragraph (c) introductory text.

■ b. Redesignating paragraphs (c)(4) through (c)(6) as paragraphs (c)(5) through (c)(7).

■ c. Adding new paragraph (c)(4).

■ d. Adding paragraph (c)(8).

The revisions and additions read as follows:

§ 63.7141 Who implements and enforces this subpart?

* * * * *

(c) The authorities that will not be delegated to state, local, or tribal agencies are as specified in paragraphs (c)(1) through (8) of this section.

* * * * *

(4) Approval of alternatives to the work practices in § 63.7090(c).

* * * * *

(8) Approval of an alternative to any electronic reporting to the EPA required by this subpart.

■ 15. Section 63.7142 is amended by:

■ a. Revising paragraph (a)(1);

■ b. Redesignating paragraphs (a)(2) and (3) as paragraphs (a)(3) and (4);

■ c. Adding new paragraph (a)(2);

■ d. Revising newly designated paragraph (a)(4) introductory text, and paragraphs (a)(4)(i), and (a)(4)(v);

■ e. Redesignating paragraphs (b)(2) and (b)(3) as paragraphs (b)(3) and (b)(4);

■ f. Adding new paragraph (b)(2); and

■ g. Revising newly designated paragraphs (b)(3) and (4).

The revisions and additions read as follows:

§ 63.7142 What are the requirements for claiming area source status?

(a) * * *

(1) EPA Method 320 of appendix A to this part, or

(2) As an alternative to EPA Method 320, ASTM D6348–12e1, Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy (incorporated by reference, see § 63.14), provided that the provisions of paragraphs (a)(2)(i) and (ii) of this section are followed:

(i) The test plan preparation and implementation in the Annexes to ASTM D 6348–12e1, Sections A1 through A8 are mandatory.

(ii) In ASTM D6348–12e1 Annex A5 (Analyte Spiking Technique), the percent recovery (%R) must be determined for each target analyte (Equation A5.5). In order for the test data to be acceptable for a compound, %R must be greater than or equal to 70 percent and less than or equal to 130 percent. If the %R value does not meet this criterion for a target compound, the test data are not acceptable for that compound and the test must be repeated for that analyte (i.e., the sampling and/or analytical procedure should be adjusted before a retest). The %R value for each compound must be reported in the test report, and all field measurements must be corrected with the calculated %R value for that compound by using the following equation: Reported Results = ((Measured Concentration in the Stack)) / (%R) × 100; or

* * * * *

(4) As an alternative to EPA Method 321, ASTM Method D6735–01 (Reapproved 2009), Standard Test Method for Measurement of Gaseous Chlorides and Fluorides from Mineral Calcining Exhaust Sources—Impinger Method (incorporated by reference, see § 63.14), provided that the provisions in paragraphs (a)(4)(i) through (vi) of this section are followed.

(i) A test must include three or more runs in which a pair of samples is obtained simultaneously for each run according to section 11.2.6 of ASTM Method D6735–01 (Reapproved 2009).

* * * * *

(v) The post-test analyte spike procedure of section 11.2.7 of ASTM Method D6735–01 (Reapproved 2009) is conducted, and the percent recovery is

calculated according to section 12.6 of ASTM Method D6735–01 (Reapproved 2009).

* * * * *

(b) * * *

(2) As an alternative to Method 320, ASTM D6348–12e1, Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy (incorporated by reference, see § 63.14), provided that the provisions of paragraphs (b)(2)(i) and (ii) of this section are followed:

(i) The test plan preparation and implementation in the Annexes to ASTM D 6348–12e1, Sections A1 through A8 are mandatory.

(ii) In ASTM D6348–12e1 Annex A5 (Analyte Spiking Technique), the percent recovery (%R) must be determined for each target analyte (Equation A5.5). In order for the test data to be acceptable for a compound, %R must be greater than or equal to 70 percent and less than or equal to 130 percent. If the %R value does not meet this criterion for a target compound, the test data are not acceptable for that compound and the test must be repeated for that analyte (*i.e.*, the sampling and/or analytical procedure should be adjusted before a retest). The %R value for each compound must be reported in the test report, and all field measurements must be corrected with the calculated %R value for that

compound by using the following equation: Reported Results = ((Measured Concentration in the Stack)) / (%R) × 100;

(3) Method 18 of appendix A–6 to part 60 of this chapter; or

(4) As an alternative to Method 18, ASTM D6420–99 (Reapproved 2010), Standard Test Method for Determination of Gaseous Organic Compounds by Direct Interface Gas Chromatography–Mass Spectrometry (GC/MS) (incorporated by reference, see § 63.14), provided that the provisions of paragraphs (b)(4)(i) through (iii) of this section are followed:

(i) The target compound(s) are those listed in section 1.1 of ASTM D6420–99 (Reapproved 2010) as measurable;

(ii) This ASTM should not be used for methane and ethane because their atomic mass is less than 35; and

(iii) ASTM D6420 (Reapproved 2010) should never be specified as a total VOC.

* * * * *

■ 16. Section 63.7143 is amended by:

■ a. Revising paragraph (3) under the definition of “Deviation.”

■ b. Revising the definition of “Emission limitation.”

■ c. Adding in alphabetical order definitions for “Shutdown” and “Startup.”

The revisions read as follows:

§ 63.7143 What definitions apply to this subpart?

* * * * *

Deviation * * *

* * * * *

(3) Prior to [Date 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**] fails to meet any emission limitation (including any operating limit or work practice) in this subpart during startup, shutdown, or malfunction, regardless of whether or not such failure is allowed by this subpart.

Emission limitation means any emission limit, opacity limit, operating limit, work practice, or VE limit.

* * * * *

Shutdown means the cessation of kiln operation. Shutdown begins when feed to the kiln is halted and ends when continuous kiln rotation ceases.

* * * * *

Startup means the time from when a shutdown kiln first begins firing fuel. Startup begins when a shutdown kiln turns on the induced draft fan and begins firing fuel in the main burner. Startup ends 60 minutes after the lime kiln generates lime product.

* * * * *

■ 17. Table 1 to subpart AAAAA is revised to read as follows:

TABLE 1 TO SUBPART AAAAA OF PART 63—EMISSION LIMITS

As required in § 63.7090(a), you must meet each emission limit in the following table that applies to you.

For . . .	You must meet the following emission limit
1. Existing lime kilns and their associated lime coolers that did not have a wet scrubber installed and operating prior to January 5, 2004.	PM emissions must not exceed 0.12 pounds per ton of stone feed (lb/tsf).
2. Existing lime kilns and their associated lime coolers that have a wet scrubber, where the scrubber itself was installed and operating prior to January 5, 2004.	PM emissions must not exceed 0.60 lb/tsf. If, at any time after January 5, 2004, the kiln changes to a dry control system, then the PM emission limit in item 1 of this Table 1 applies, and the kiln is hereafter ineligible for the PM emission limit in item 2 of this Table 1 regardless of the method of PM control.
3. New lime kilns and their associated lime coolers	PM emissions must not exceed 0.10 lb/tsf.
4. All existing and new lime kilns and their associated coolers at your LMP, and you choose to average PM emissions, except that any kiln that is allowed to meet the 0.60 lb/tsf PM emission limit is ineligible for averaging.	Weighted average PM emissions calculated according to Eq. 2 in § 63.7112 must not exceed 0.12 lb/tsf (if you are averaging only existing kilns) or 0.10 lb/tsf (if you are averaging only new kilns). If you are averaging existing and new kilns, your weighted average PM emissions must not exceed the weighted average emission limit calculated according to Eq. 3 in § 63.7112, except that no new kiln and its associated cooler considered alone may exceed an average PM emissions limit of 0.10 lb/tsf.
5. All new and existing lime kilns and their associated coolers during startup and shutdown.	After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register], work practices in § 63.7090(c).
6. Stack emissions from all PSH operations at a new or existing affected source.	PM emissions must not exceed 0.05 grams per dry standard cubic meter (g/dscm).
7. Stack emissions from all PSH operations at a new or existing affected source, unless the stack emissions are discharged through a wet scrubber control device.	Emissions must not exceed 7 percent opacity.
8. Fugitive emissions from all PSH operations at a new or existing affected source, except as provided by item 9 of this Table 1.	Emissions must not exceed 10 percent opacity.
9. All PSH operations at a new or existing affected source enclosed in a building.	All of the individually affected PSH operations must comply with the applicable PM and opacity emission limitations in items 6 through 8 of this Table 1, or the building must comply with the following: There must be no VE from the building, except from a vent; and vent emissions must not exceed the stack emissions limitations in items 6 and 7 of this Table 1.

TABLE 1 TO SUBPART AAAAA OF PART 63—EMISSION LIMITS—Continued

As required in § 63.7090(a), you must meet each emission limit in the following table that applies to you.

For . . .	You must meet the following emission limit
10. Each FF that controls emissions from only an individual, enclosed storage bin.	Emissions must not exceed 7 percent opacity.
11. Each set of multiple storage bins at a new or existing affected source, with combined stack emissions.	You must comply with the emission limits in items 6 and 7 of this Table 1.

■ 18. Table 2 of subpart AAAAA is amended by adding an entry for “7” to read as follows:

TABLE 2 TO SUBPART AAAAA OF PART 63—OPERATING LIMITS

As required in § 63.7090(b), you must meet each operating limit in the following table that applies to you.

For . . .	You must . . .
7. During startup and shutdown, each lime kiln and each lime cooler (if there is a separate exhaust to the atmosphere from the associated lime cooler) subject to an emission limit that is equipped with an add-on air pollution control device.	After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register], meet the work practice requirements in § 63.7090(c).

■ 19. Revise Table 4 to subpart AAAAA to read as follows:

TABLE 4 TO SUBPART AAAAA OF PART 63—REQUIREMENTS FOR PERFORMANCE TESTS

As required in § 63.7112, you must conduct each performance test in the following table that applies to you.

For . . .	You must . . .	Using . . .	According to the following requirements . . .
1. Each lime kiln and each associated lime cooler, if there is a separate exhaust to the atmosphere from the associated lime cooler.	Select the location of the sampling port and the number of traverse ports.	Method 1 or 1A of appendix A to part 60 of this chapter; and § 63.6(d)(1)(i).	Sampling sites must be located at the outlet of the control device(s) and prior to any releases to the atmosphere.
2. Each lime kiln and each associated lime cooler, if there is a separate exhaust to the atmosphere from the associated lime cooler.	Determine velocity and volumetric flow rate.	Method 2, 2A, 2C, 2D, 2F, or 2G in appendix A to part 60 of this chapter.	Not applicable.
3. Each lime kiln and each associated lime cooler, if there is a separate exhaust to the atmosphere from the associated lime cooler.	Conduct gas molecular weight analysis.	Method 3, 3A, or 3B in appendix A to part 60 of this chapter.	You may use ASME PTC 19.10–1981 (2010)—Part 10 ^a as an alternative to using the manual procedures (but not instrumental procedures) in Method 3B.
4. Each lime kiln and each associated lime cooler, if there is a separate exhaust to the atmosphere from the associated lime cooler.	Measure moisture content of the stack gas.	Method 4 in appendix A to part 60 of this chapter.	Not applicable.

TABLE 4 TO SUBPART AAAAA OF PART 63—REQUIREMENTS FOR PERFORMANCE TESTS—Continued

As required in § 63.7112, you must conduct each performance test in the following table that applies to you.

For . . .	You must . . .	Using . . .	According to the following requirements . . .
5. Each lime kiln and each associated lime cooler, if there is a separate exhaust to the atmosphere from the associated lime cooler, and which uses a negative pressure PM control device.	Measure PM emissions.	Method 5 in appendix A to part 60 of this chapter.	Conduct the test(s) when the source is operating at representative operating conditions in accordance with § 63.7(e) before [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register] and § 63.7112(b) after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register]; the minimum sampling volume must be 0.85 dry standard cubic meter (dscm) (30 dry standard cubic foot (dscf)); if there is a separate lime cooler exhaust to the atmosphere, you must conduct the Method 5 test of the cooler exhaust concurrently with the kiln exhaust test.
6. Each lime kiln and each associated lime cooler, if there is a separate exhaust to the atmosphere from the associated lime cooler, and which uses a positive pressure FF or ESP.	Measure PM emissions.	Method 5D in appendix A to part 60 of this chapter.	Conduct the test(s) when the source is operating at representative operating conditions in accordance with § 63.7(e) [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register] and § 63.7112(b) after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register]; if there is a separate lime cooler exhaust to the atmosphere, you must conduct the Method 5 test of the separate cooler exhaust concurrently with the kiln exhaust test.
7. Each lime kiln	Determine the mass rate of stone feed to the kiln during the kiln PM emissions test.	Any suitable device	Calibrate and maintain the device according to manufacturer's instructions; the measuring device used must be accurate to within ± 5 percent of the mass rate of stone feed over its operating range.
8. Each lime kiln equipped with a wet scrubber.	Establish the operating limit for the average gas stream pressure drop across the wet scrubber.	Data for the gas stream pressure drop measurement device during the kiln PM performance test.	The continuous pressure drop measurement device must be accurate within plus or minus 1 percent; you must collect the pressure drop data during the period of the performance test and determine the operating limit according to § 63.7112(j).
9. Each lime kiln equipped with a wet scrubber.	Establish the operating limit for the average liquid flow rate to the scrubber.	Data from the liquid flow rate measurement device during the kiln PM performance test.	The continuous scrubbing liquid flow rate measuring device must be accurate within plus or minus 1 percent; you must collect the flow rate data during the period of the performance test and determine the operating limit according to § 63.7112(j).
10. Each lime kiln equipped with a FF or ESP that is monitored with a PM detector.	Have installed and have operating the BLDS or PM detector prior to the performance test.	Standard operating procedures incorporated into the OM&M plan.	According to the requirements in § 63.7113(d) or (e), respectively.
11. Each lime kiln equipped with a FF or ESP that is monitored with a COMS.	Have installed and have operating the COMS prior to the performance test.	Standard operating procedures incorporated into the OM&M plan and as required by 40 CFR part 63, subpart A, General Provisions and according to PS-1 of appendix B to part 60 of this chapter, except as specified in § 63.7113(g)(2).	According to the requirements in § 63.7113(g).
12. Each stack emission from a PSH operation, vent from a building enclosing a PSH operation, or set of multiple storage bins with combined stack emissions, which is subject to a PM emission limit.	Measure PM emissions.	Method 5 or Method 17 in appendix A to part 60 of this chapter.	The sample volume must be at least 1.70 dscm (60 dscf); for Method 5, if the gas stream being sampled is at ambient temperature, the sampling probe and filter may be operated without heaters; and if the gas stream is above ambient temperature, the sampling probe and filter may be operated at a temperature high enough, but no higher than 121 °C (250 °F), to prevent water condensation on the filter (Method 17 may be used only with exhaust gas temperatures of not more than 250 °F).

TABLE 4 TO SUBPART AAAAA OF PART 63—REQUIREMENTS FOR PERFORMANCE TESTS—Continued

As required in § 63.7112, you must conduct each performance test in the following table that applies to you.

For . . .	You must . . .	Using . . .	According to the following requirements . . .
13. Each stack emission from a PSH operation, vent from a building enclosing a PSH operation, or set of multiple storage bins with combined stack emissions, which is subject to an opacity limit.	Conduct opacity observations.	Method 9 in appendix A to part 60 of this chapter.	The test duration must be for at least 3 hours and you must obtain at least thirty, 6-minute averages.
14. Each stack emissions source from a PSH operation subject to a PM or opacity limit, which uses a wet scrubber.	Establish the average gas stream pressure drop across the wet scrubber.	Data for the gas stream pressure drop measurement device during the PSH operation stack PM performance test.	The pressure drop measurement device must be accurate within plus or minus 1 percent; you must collect the pressure drop data during the period of the performance test and determine the operating limit according to § 63.7112(j).
15. Each stack emissions source from a PSH operation subject to a PM or opacity limit, which uses a wet scrubber.	Establish the operating limit for the average liquid flow rate to the scrubber.	Data from the liquid flow rate measurement device during the PSH operation stack PM performance test.	The continuous scrubbing liquid flow rate measuring device must be accurate within plus or minus 1 percent; you must collect the flow rate data during the period of the performance test and determine the operating limit according to § 63.7112(j).
16. Each FF that controls emissions from only an individual, enclosed, new or existing storage bin.	Conduct opacity observations.	Method 9 in appendix A to part 60 of this chapter.	The test duration must be for at least 1 hour and you must obtain ten 6-minute averages.
17. Fugitive emissions from any PSH operation subject to an opacity limit.	Conduct opacity observations.	Method 9 in appendix A to part 60 of this chapter.	The test duration must be for at least 3 hours, but the 3-hour test may be reduced to 1 hour if, during the first 1-hour period, there are no individual readings greater than 10 percent opacity and there are no more than three readings of 10 percent during the first 1-hour period.
18. Each building enclosing any PSH operation, that is subject to a VE limit.	Conduct VE check	The specifications in § 63.7112(k)	The performance test must be conducted while all affected PSH operations within the building are operating; the performance test for each affected building must be at least 75 minutes, with each side of the building and roof being observed for at least 15 minutes.

^a Incorporated by reference, see § 63.14.

■ 20. Table 7 of subpart AAAAA is revised to read as follows:

TABLE 7 TO SUBPART AAAAA OF PART 63—REQUIREMENTS FOR REPORTS

As required in § 63.7131, you must submit each report in this table that applies to you.

You must submit a . . .	The report must contain . . .	You must submit the report . . .
1. Compliance report	a. If there are no deviations from any emission limitations (emission limit, operating limit, work practice, opacity limit, and VE limit) that applies to you, a statement that there were no deviations from the emission limitations during the reporting period; b. If there were no periods during which the CMS, including any operating parameter monitoring system, was out-of-control as specified in § 63.8(c)(7), a statement that there were no periods during which the CMS was out-of-control during the reporting period; c. If you have a deviation from any emission limitation (emission limit, operating limit, work practice, opacity limit, and VE limit) during the reporting period, the report must contain the information in § 63.7131(d);	Semiannually according to the requirements in § 63.7131(b). Semiannually according to the requirements in § 63.7131(b). Semiannually according to the requirements in § 63.7131(b).

TABLE 7 TO SUBPART AAAAA OF PART 63—REQUIREMENTS FOR REPORTS—Continued

As required in § 63.7131, you must submit each report in this table that applies to you.

You must submit a . . .	The report must contain . . .	You must submit the report . . .
	d. If there were periods during which the CMS, including any operating parameter monitoring system, was out-of-control, as specified in § 63.8(c)(7), the report must contain the information in § 63.7131(e); and.	Semiannually according to the requirements in § 63.7131(b).
	e. Before [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register], if you had a startup, shutdown or malfunction during the reporting period and you took actions consistent with your SSMP, the compliance report must include the information in § 63.10(d)(5)(i). After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register], if you had a startup, shutdown or malfunction during the reporting period and you failed to meet an applicable standard, the compliance report must include the information in § 63.7131(c)(3)..	Semiannually according to the requirements in § 63.7131(b).
2. Before [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register], an immediate startup, shutdown, and malfunction report if you had a startup, shutdown, or malfunction during the reporting period that is not consistent with your SSMP.	Actions taken for the event	By fax or telephone within 2 working days after starting actions inconsistent with the SSMP.
3. Before [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register], an immediate startup, shutdown, and malfunction report if you had a startup, shutdown, or malfunction during the reporting period that is not consistent with your SSMP.	The information in § 63.10(d)(5)(ii)	By letter within 7 working days after the end of the event unless you have made alternative arrangements with the permitting authority. See § 63.10(d)(5)(ii).
(4) Performance Test Report	The information required in § 63.7(g)	According to the requirements of § 63.7131

■ 20. Table 8 of subpart AAAAA is revised to read as follows:

TABLE 8 TO SUBPART AAAAA OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART AAAAA

As required in § 63.7140, you must comply with the applicable General Provisions requirements according to the following table:

Citation	Summary of requirement	Am I subject to this requirement?	Explanations
§ 63.1(a)(1)–(4)	Applicability	Yes.	§§ 63.7081 and 63.7142 specify additional applicability determination requirements.
§ 63.1(a)(5)		No.	
§ 63.1(a)(6)	Applicability	Yes.	
§ 63.1(a)(7)–(a)(9)		No.	
§ 63.1(a)(10)–(a)(14)	Applicability	Yes.	
§ 63.1(b)(1)	Initial Applicability Determination	Yes	Area sources not subject to subpart AAAAA, except all sources must make initial applicability determination.
§ 63.1(b)(2)		No.	
§ 63.1(b)(3)	Initial Applicability Determination	Yes.	
§ 63.1(c)(1)	Applicability After Standard Established.	Yes.	
§ 63.1(c)(2)	Permit Requirements	No	
§ 63.1(c)(3)–(4)		No.	Additional definitions in § 63.7143.
§ 63.1(c)(5)	Area Source Becomes Major	Yes.	
§ 63.1(d)		No.	
§ 63.1(e)	Applicability of Permit Program	Yes.	
§ 63.2	Definitions	Yes	
§ 63.3(a)–(c)	Units and Abbreviations	Yes.	
§ 63.4(a)(1)–(a)(2)	Prohibited Activities	Yes.	
§ 63.4(a)(3)–(a)(5)		No.	
§ 63.4(b)–(c)	Circumvention, Severability	Yes.	
§ 63.5(a)(1)–(2)	Construction/Reconstruction	Yes.	
§ 63.5(b)(1)	Compliance Dates	Yes.	

TABLE 8 TO SUBPART AAAAA OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART AAAAA—Continued
As required in § 63.7140, you must comply with the applicable General Provisions requirements according to the following table:

Citation	Summary of requirement	Am I subject to this requirement?	Explanations
§ 63.5(b)(2)		No.	
§ 63.5(b)(3)–(4)	Construction Approval, Applicability	Yes.	
§ 63.5(b)(5)		No.	
§ 63.5(b)(6)	Applicability	Yes.	
§ 63.5(c)		No.	
§ 63.5(d)(1)–(4)	Approval of Construction/Reconstruction.	Yes.	
§ 63.5(e)	Approval of Construction/Reconstruction.	Yes.	
§ 63.5(f)(1)–(2)	Approval of Construction/Reconstruction.	Yes.	
§ 63.6(a)	Compliance for Standards and Maintenance.	Yes.	
§ 63.6(b)(1)–(5)	Compliance Dates	Yes.	
§ 63.6(b)(6)		No.	
§ 63.6(b)(7)	Compliance Dates	Yes.	
§ 63.6(c)(1)–(2)	Compliance Dates	Yes.	
§ 63.6(c)(3)–(c)(4)		No.	
§ 63.6(c)(5)	Compliance Dates	Yes.	
§ 63.6(d)		No.	
§ 63.6(e)(1)(i)	General Duty to Minimize Emissions ...	Yes before [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register]. No after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register].	After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register], see § 63.7100 for general duty requirement.
§ 63.6(e)(1)(ii)	Requirement to Correct Malfunctions ASAP.	Yes before [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register] No after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register].	
§ 63.6(e)(1)(iii)	Operation and Maintenance Requirements.	Yes.	
§ 63.6(e)(2)		No	[Reserved]
§ 63.6(e)(3)	Startup, Shutdown Malfunction Plan	Yes before [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register]. No after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register].	After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register], the OM&M plan must address periods of startup and shutdown. See § 63.7100(d).
§ 63.6(f)(1)	SSM exemption	Yes before [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register]. No after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register].	After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register], for periods of startup and shutdown, see § 63.7090(c).
§ 63.6(f)(2)–(3)	Methods for Determining Compliance ..	Yes.	
§ 63.6(g)(1)–(g)(3) ..	Alternative Standard	Yes.	
§ 63.6(h)(1)	SSM exemption	Yes before [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register]. No after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register].	After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register], for periods of startup and shutdown, see § 63.7090(c).
§ 63.6(h)(2)	Methods for Determining Compliance ..	Yes.	
§ 63.6(h)(3)		No.	
§ 63.6(h)(4)–(h)(5)(i) ..	Opacity/VE Standards	Yes	
§ 63.6(h)(5) (ii)–(iii) ..	Opacity/VE Standards	No	This requirement only applies to opacity and VE performance checks required in Table 4 to subpart AAAAA. Test durations are specified in subpart AAAAA; subpart AAAAA takes precedence.
§ 63.6(h)(5)(iv)	Opacity/VE Standards	No.	
§ 63.6(h)(5)(v)	Opacity/VE Standards	Yes.	
§ 63.6(h)(6)	Opacity/VE Standards	Yes.	
§ 63.6(h)(7)	COM Use	Yes.	
§ 63.6(h)(8)	Compliance with Opacity and VE	Yes.	
§ 63.6(h)(9)	Adjustment of Opacity Limit	Yes.	
§ 63.6(i)(1)–(i)(14) ...	Extension of Compliance	Yes.	

TABLE 8 TO SUBPART AAAAA OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART AAAAA—Continued
As required in § 63.7140, you must comply with the applicable General Provisions requirements according to the following table:

Citation	Summary of requirement	Am I subject to this requirement?	Explanations
§ 63.6(i)(15)		No.	
§ 63.6(i)(16)	Extension of Compliance	Yes.	
§ 63.6(j)	Exemption from Compliance	Yes.	
§ 63.7(a)(1)–(a)(3) ...	Performance Testing Requirements ...	Yes	§ 63.7110 specifies deadlines; § 63.7112 has additional specific requirements.
§ 63.7(b)	Notification	Yes.	
§ 63.7(c)	Quality Assurance/Test Plan	Yes.	
§ 63.7(d)	Testing Facilities	Yes.	
§ 63.7(e)(1)	Conduct of Tests	Yes before [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register]. No after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register].	After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register], see § 63.7112(b).
§ 63.7(e)(2)–(4)	Conduct of Tests	Yes.	
§ 63.7(f)	Alternative Test Method	Yes.	
§ 63.7(g)	Data Analysis	Yes.	
§ 63.7(h)	Waiver of Tests	Yes.	
§ 63.8(a)(1)	Monitoring Requirements	Yes	See § 63.7113.
§ 63.8(a)(2)	Monitoring	Yes.	
§ 63.8(a)(3)		No.	
§ 63.8(a)(4)	Monitoring	No	Flares not applicable.
§ 63.8(b)(1)–(3)	Conduct of Monitoring	Yes.	
§ 63.8(c)(1)(i)	CMS Operation/Maintenance	Yes before [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register]. No after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register].	After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register], see § 63.7100 for OM&M requirements.
§ 63.8(c)(1)(ii)	CMS Spare Parts	Yes.	
§ 63.8(c)(1)(iii)	Requirement to Develop SSM Plan for CMS.	Yes before [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register]. No after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register].	After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register], no longer required.
§ 63.8(c)(2)–(3)	CMS Operation/Maintenance	Yes.	
§ 63.8(c)(4)	CMS Requirements	No	See § 63.7121.
§ 63.8(c)(4)(i)–(ii)	Cycle Time for COM and CEMS	Yes	No CEMS are required under subpart AAAAA; see § 63.7113 for CPMS requirements.
§ 63.8(c)(5)	Minimum COM procedures	Yes	COM not required.
§ 63.8(c)(6)	CMS Requirements	No	See § 63.7113.
§ 63.8(c)(7)–(8)	CMS Requirements	Yes.	
§ 63.8(d)(1)–(2)	Quality Control	Yes	See also § 63.7113.
§ 63.8(d)(3)	Quality Control	Yes before [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register]. No after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register].	
§ 63.8(e)	Performance Evaluation for CMS	Yes.	See also § 63.7113
§ 63.8(f)(1)–(f)(5)	Alternative Monitoring Method	Yes.	
§ 63.8(f)(6)	Alternative to Relative Accuracy Test for CEMS.	No	No CEMS required in subpart AAAAA.
§ 63.8(g)(1)–(g)(5) ...	Data Reduction; Data That Cannot Be Used.	No	See data reduction requirements in §§ 63.7120 and 63.7121.
§ 63.9(a)	Notification Requirements	Yes.	See § 63.7130.
§ 63.9(b)	Initial Notifications	Yes.	
§ 63.9(c)	Request for Compliance Extension	Yes.	
§ 63.9(d)	New Source Notification for Special Compliance Requirements.	Yes.	
§ 63.9(e)	Notification of Performance Test	Yes.	
§ 63.9(f)	Notification of VE/Opacity Test	Yes	This requirement only applies to opacity and VE performance tests required in Table 4 to subpart AAAAA. Notification not required for VE/opacity test under Table 6 to subpart AAAAA.

TABLE 8 TO SUBPART AAAAA OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART AAAAA—Continued
As required in § 63.7140, you must comply with the applicable General Provisions requirements according to the following table:

Citation	Summary of requirement	Am I subject to this requirement?	Explanations
§ 63.9(g)	Additional CMS Notifications	No	Not required for operating parameter monitoring.
§ 63.9(h)(1)–(h)(3) ...	Notification of Compliance Status	Yes.	
§ 63.9(h)(4)		No.	
§ 63.9(h)(5)–(h)(6) ...	Notification of Compliance Status	Yes.	
§ 63.9(i)	Adjustment of Deadlines	Yes.	
§ 63.9(j)	Change in Previous Information	Yes.	
§ 63.10(a)	Recordkeeping/Reporting General Requirements.	Yes	See §§ 63.7131 through 63.7133.
§ 63.10(b)(1)	Records	Yes.	
§ 63.10 (b)(2)(i)	Recordkeeping of Occurrence and Duration of Startups and Shutdowns.	Yes before [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register] No after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register].	
§ 63.10(b)(2)(ii)	Recordkeeping of Failures to Meet a Standard.	Yes before [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register]. No after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register].	After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register], see § 63.7132 for recordkeeping of (1) date, time and duration; (2) listing of affected source or equipment, and an estimate of the quantity of each regulated pollutant emitted over the standard; and (3) actions to minimize emissions and correct the failure.
§ 63.10(b)(2)(iii)	Maintenance Records	Yes.	
§ 63.10(b)(2)(iv)–(v)	Actions Taken to Minimize Emissions During SSM.	Yes before [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register]. No after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register].	After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register], see § 63.7100 for OM&M requirements.
§ 63.10(b)(2)(vi)–(xii)	Recordkeeping for CMS	Yes.	
§ 63.10(b)(2)(xiii)	Records for Relative Accuracy Test	No.	
§ 63.10(b)(2)(xiv)	Records for Notification	Yes.	
§ 63.10(b)(3)	Applicability Determinations	Yes.	
§ 63.10(c)	Additional CMS Recordkeeping	No	See § 63.7132.
§ 63.10(d)(1)	General Reporting Requirements	Yes.	
§ 63.10(d)(2)	Performance Test Results	Yes.	
§ 63.10(d)(3)	Opacity or VE Observations	Yes	For the periodic monitoring requirements in Table 6 to subpart AAAAA, report according to § 63.10(d)(3) only if VE observed and subsequent visual opacity test is required.
§ 63.10(d)(4)	Progress Reports	Yes.	
§ 63.10(d)(5)(i)	Periodic Startup, Shutdown, Malfunction Reports.	Yes before [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register]. No after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register].	After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register], see § 63.7131 for malfunction reporting requirements.
§ 63.10(d)(5)(ii)	Immediate Startup, Shutdown, Malfunction Reports.	Yes before [DATE 181 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register]. No after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE Federal Register].	
§ 63.10(e)	Additional CMS Reports	No	See specific requirements in subpart AAAAA, see § 63.7131.
§ 63.10(f)	Waiver for Recordkeeping/Reporting ...	Yes.	
§ 63.11(a)–(b)	Control Device and Work Practice Requirements.	No	Flares not applicable.
§ 63.12(a)–(c)	State Authority and Delegations	Yes.	
§ 63.13(a)–(c)	State/Regional Addresses	Yes.	
§ 63.14(a)–(b)	Incorporation by Reference	No.	
§ 63.15(a)–(b)	Availability of Information and Confidentiality.	Yes.	
§ 63.16	Performance Track Provisions	Yes.	

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Part III

Nuclear Regulatory Commission

10 CFR Part 26

Fitness for Duty Drug Testing Requirements; Proposed Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Part 26

[NRC-2009-0225]

RIN 3150-A167

Fitness for Duty Drug Testing Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule and draft regulatory guide; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations regarding fitness for duty (FFD) programs for certain NRC licensees and other entities to more closely align the NRC's drug testing requirements with the updates made to the U.S. Department of Health and Human Services "Mandatory Guidelines for Federal Workplace Drug Testing Programs" in 2008, which became effective on October 1, 2010. The proposed rule would also incorporate lessons learned from implementation of the NRC's current FFD regulations. These changes would enhance the ability of NRC licensees and other entities to identify individuals using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process. The proposed rule would also provide additional protections to individuals subject to drug testing and would improve the clarity, organization, and flexibility of the NRC's FFD regulations. The NRC is also requesting comment on draft regulatory guide 5040.

DATES: Submit comments by December 2, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2009-0225. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; email: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule.

- *Email comments to:* Rulemaking.Comments@nrc.gov. If you do not receive an automatic email reply

confirming receipt, then contact us at 301-415-1677.

- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301-415-1677.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Stewart Schneider, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-4123; email: Stewart.Schneider@nrc.gov; Brian Zaleski, Office of Nuclear Security and Incident Response, telephone: 301-287-0638; email: Brian.Zaleski@nrc.gov; or Paul Harris, Office of Nuclear Security and Incident Response, telephone: 301-287-9294; email: Paul.Harris@nrc.gov; U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

Executive Summary

A. Need for the Regulatory Action

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations regarding fitness for duty (FFD) programs for certain NRC licensees and other entities to more closely align the NRC's drug testing requirements with the updates made in 2008 to the U.S. Department of Health and Human Services (HHS) "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (HHS Guidelines), which were published in the **Federal Register** on November 25, 2008 (73 FR 71858), corrected on December 10, 2008 (73 FR 75122), and became effective on October 1, 2010 (75 FR 22809; April 30, 2010). The HHS Guidelines govern Federal employee workplace drug testing programs at more than 100 Federal agencies and Federal agency drug testing programs (e.g., U.S. Department of Transportation (DOT)) that test civilians in safety- and security-sensitive positions similar to personnel tested under part 26, "Fitness for Duty Programs," in title 10 of the *Code of Federal Regulations* (10 CFR). More closely aligning the drug testing provisions under 10 CFR part 26 with the 2008 HHS Guidelines would enhance the ability of licensees and

other entities to identify individuals using illegal drugs and misusing legal drugs. The proposed rule would also incorporate lessons learned from implementation of the 10 CFR part 26 final rule published in the **Federal Register** on March 31, 2008 (73 FR 16966; hereafter referred to as "2008 FFD final rule"). These lessons include improved methods to identify attempts to subvert the drug testing process and improvements in the clarity, consistency, and flexibility of donor protections under 10 CFR part 26. Historically, the NRC has relied upon the HHS Guidelines to establish the technical requirements for urine specimen collection, drug testing, and results evaluation and has required licensees and other entities to use HHS-certified laboratories to perform drug testing. The last NRC alignment with the HHS Guidelines was completed with the 2008 FFD final rule, which incorporated provisions from the 2004 HHS Guidelines (69 FR 19643; April 13, 2004).

B. Major Provisions

Major provisions of the proposed rule include the following:

- Add initial and confirmatory drug testing for two illegal amphetamine-based controlled substances—methylenedioxymethamphetamine (MDMA) and methylenedioxyamphetamine (MDA)—referred to as Ecstasy-type drugs in this proposed rule.

- Add initial drug testing for 6-acetylmorphine (6-AM), a metabolite of the illegal drug heroin, and update the confirmatory drug testing method for 6-AM.

- Lower the drug testing cutoff levels for amphetamine, cocaine metabolite, and methamphetamine.

- Enhance the detection of subversion attempts by strengthening the testing methods used to identify drugs and drug metabolites in urine specimens with dilute validity test results and in specimens collected under direct observation.

- Require Medical Review Officers (MROs) to evaluate the elapsed time from specimen collection to testing and exposure to high temperature, as possible causes of some invalid test results due to high solvated hydrogen ion concentration (i.e., pH).

- Improve the clarity, consistency, and organization of 10 CFR part 26 by adding and updating definitions; increase flexibility by addressing personnel who may monitor a donor in a shy-bladder situation who is hydrating; and enhance both donor protections by providing additional

instructions for same-gender observers used in observed collections and due process by requiring MROs to document the date and time that an oral request is received from a donor to initiate the retesting of a specimen.

C. Costs and Benefits

The NRC prepared a draft regulatory analysis to quantify the costs and benefits of the proposed rule, as well as to examine the qualitative factors to be considered in the NRC's rulemaking decision. The analysis concluded that the proposed rule would result in net costs to the industry. The proposed rule, relative to the regulatory baseline, would result in a net cost to industry of between \$2.4 million based on a 7 percent net present value and \$3.4 million based on a 3 percent net present value. The estimated average net cost per licensee or other entity site would be a one-time cost of \$5,031 and an annual cost of \$2,516. Thirteen qualitative factors were evaluated in the draft regulatory analysis: Public health (accident), occupational health (accident), offsite property, onsite property, regulatory efficiency, safeguards and security considerations, and other considerations (public perception, public trust, worker productivity, improved protection of individual rights, work environment free of drugs and the effects of such substances, safety vulnerability, and security vulnerability). The draft regulatory analysis includes a narrative discussion of each qualitative factor.

If the results of the regulatory analysis were based solely on the costs and the benefits that could be quantified, then the regulatory analysis would show that rulemaking is not justified because the total estimated quantified benefits of the proposed regulatory action do not equal or exceed the estimated costs of the proposed regulatory action. However, when the qualitative benefits are considered, together with the quantified benefits, then the benefits outweigh the identified quantitative and qualitative impacts.

In the draft regulatory analysis, the NRC concluded that the proposed rule should be adopted because it would result in a 10- to 12-percent increase per year in the detection of individuals using drugs or attempting to subvert the drug testing process. In comparison to the test results from calendar years 2013 and 2014, the estimated increase in detection each year is equivalent to identifying approximately 95 additional individuals using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process. This improved detection would prevent

drug-using individuals from gaining or maintaining unescorted access authorization to NRC-licensed facilities (i.e., operating nuclear power reactors, nuclear power reactors under construction, and Category I fuel cycle facilities) and other locations (e.g., Emergency Operations Facilities, Technical Support Centers). In addition, the enhanced detection would prevent drug-using individuals from gaining or maintaining unescorted access authorization to special strategic nuclear material (SSNM) or sensitive information. An enhanced drug testing program might also deter drug-using individuals from seeking employment in 10 CFR part 26 regulated positions and/or incentivize those already in regulated positions to cease drug use or to seek medical assistance to address an addiction or misuse issue.

For more information, please see the regulatory analysis (Accession No. ML19169A115 in the NRC's Agencywide Documents Access and Management System (ADAMS)).

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2009-0225 when contacting the NRC about the availability of information for this action. You may obtain publicly-

available information related to this action by any of the following methods:

- *Federal Rulemaking Website*: Go to <https://www.regulations.gov> and search for Docket ID NRC-2009-0225.
- *NRC's Agencywide Documents Access and Management System (ADAMS)*: You may obtain publicly-available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to pdr.resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the "Availability of Documents" section.
- *NRC's PDR*: You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC-2009-0225 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <https://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

A. The Health and Human Services Guidelines

Through Executive Order 12564 (51 FR 32889; September 17, 1986), the President of the United States designated the Department of Health and Human Services (HHS) as the Federal agency responsible for establishing and maintaining the requirements and guidance for conducting Federal employee workplace

drug testing. In execution of this designation, and under the authority of Section 503 of Public Law 100–71, 5 U.S.C. Section 7301 notes, HHS developed the “Mandatory Guidelines for Federal Workplace Drug Testing Programs” (HHS Guidelines) that established a robust legal framework to conduct drug testing to provide the following: Reasonable assurance of donor privacy; drug testing accuracy and precision; specimen collection, custody, and control; and results review by a Medical Review Officer (MRO).

The HHS Guidelines also established the certification requirements that each laboratory must meet to test specimens for Federal employee workplace drug testing programs. To obtain certification, a laboratory must successfully complete several rounds of performance testing and a National Laboratory Certification Program (NLCP) inspection. The certification requirements include, but are not limited to, laboratory staffing and qualifications, testing procedures, quality assurance and quality control, and results reporting. Once certified, each laboratory is subject to quarterly performance testing and NLCP inspection every 6 months to verify adherence to the HHS Guidelines. The HHS laboratory certification process provides assurance to the NRC, licensees, and other entities that the testing of specimens, under 10 CFR part 26, is conducted with the highest standards of accuracy, precision, and quality.

Periodically, HHS updates the HHS Guidelines to enhance testing program effectiveness based on advances in drug testing technologies, processes, methodologies, and instrumentation; revise the authorized substances in the testing panel as societal drug-use trends change; and incorporate lessons learned from the NLCP. Each revision of the HHS Guidelines is published following a rigorous process that includes scientific, policy, legal, and technical review by the independent Drug Testing Advisory Board, which advises the Administrator of the HHS Substance Abuse and Mental Health Services Administration (SAMHSA); academic peer reviews; public review and comment; and input from Federal agencies that implement the HHS Guidelines. The HHS also conducts extensive outreach with affected stakeholders and researches societal drug-use trends to promulgate effective drug testing methods.

The HHS Guidelines govern the drug testing programs of over 100 Federal agencies that test Federal employees; are used by many Federal agencies that test civilians in safety- and security-

sensitive positions similar to personnel tested under 10 CFR part 26, such as the U.S. Department of Transportation (DOT); and by many private entities. The NRC has historically relied on HHS to establish the technical requirements for urine specimen collection, specimen testing and test result evaluation, and in general only deviates from the HHS Guidelines for considerations specific to the nuclear industry. The NRC relies on the HHS Guidelines as part of its technical basis for the drug testing requirements contained under 10 CFR part 26. Updating 10 CFR part 26 to align with changes in the 2008 HHS Guidelines would help to ensure that the NRC’s regulations continue to be scientifically and technically sound.

B. History of the NRC’s Fitness for Duty Program

In the 1970s, the NRC and the commercial nuclear power industry began addressing concerns about the potential public health and safety impacts of fitness for duty (FFD) problems at nuclear power plants. Most nuclear utilities voluntarily implemented FFD programs during the 1980s, and the NRC monitored the comprehensiveness and effectiveness of these programs. On August 4, 1986 (51 FR 27921), the NRC published the Commission Policy Statement on Fitness for Duty of Nuclear Power Plant Personnel, which outlined the need for nuclear power plant licensees to implement programs to address FFD problems—including illegal drug use, alcohol abuse, misuse of legal drugs, and any other mental or physical problems that could impair job performance. An evaluation of licensee programs following the implementation of the policy statement identified a wide range in the quality and comprehensiveness of licensee FFD testing programs that ultimately resulted in the NRC’s decision to pursue rulemaking.

The NRC published a final rule, entitled “Fitness-for-Duty Programs,” in the **Federal Register** on June 7, 1989 (54 FR 24468), adding 10 CFR part 26. The 1989 FFD final rule was based on the 1988 version of the HHS Guidelines (53 FR 11970; April 11, 1988). A subsequent final rule, published in the **Federal Register** on June 3, 1993 (58 FR 31467), expanded the scope of 10 CFR part 26 to include licensees authorized to possess, use, or transport formula quantities of strategic special nuclear materials (SSNM).

The NRC issued the first substantial revision to 10 CFR part 26 in a final rule on March 31, 2008 (73 FR 16966; hereafter referred to as the “2008 FFD

final rule”). The 2008 FFD final rule updated the NRC’s drug testing requirements to align with the then-latest HHS Guidelines, which were issued in 2004 (69 FR 19644; April 13, 2004). The 10 CFR part 26 updates included the following: (1) Required validity testing of each specimen to address the potential for subversion of the testing process, (2) advancements in drug and alcohol testing technologies, (3) changes to drug and alcohol testing cutoff levels, and (4) lessons learned from the implementation of 10 CFR part 26 since its addition in 1989.

On November 25, 2008, HHS issued the 2008 HHS Guidelines (73 FR 71858), which included the following: (1) An expanded drug testing panel, (2) lower drug testing cutoff levels for some substances, (3) advances in testing technologies, and (4) more detailed requirements for specimen collectors and MROs. The 2008 HHS Guidelines became effective on October 1, 2010. The 2008 Guidelines’ updates to the 2004 Guidelines are currently not reflected in 10 CFR part 26.

III. Discussion

A. The Need for Rulemaking

1. Alignment With the 2008 Health and Human Services Guidelines

In the 2008 HHS Guidelines, HHS enhanced the detection of illegal drug use and the misuse of prescription drugs through the following changes: (1) Lowering the initial and confirmatory testing cutoff levels for amphetamine, cocaine, and methamphetamine; (2) establishing an initial testing requirement and revising the confirmatory testing cutoff level for the heroin metabolite 6-AM; and (3) establishing testing for Ecstasy-type drugs (which are part of the amphetamine class of drugs).

The effectiveness of the 2008 HHS Guidelines is demonstrated by the enhanced detection evident in the test results reported by HHS, the DOT, and Quest Diagnostics® (Quest), which is an HHS-certified laboratory that conducts testing for both Federal workplace drug testing programs (*i.e.*, Federally-mandated) and private company testing programs (*i.e.*, U.S. general workforce). Quest annually publishes a Drug Testing Index™ report, which presents Quest laboratory testing results for Federally-mandated drug tests. On March 13, 2012, Quest reported a 33 percent increase from 2010 to 2011 in cocaine positive test results for 1.6 million Federal workplace tests conducted. Quest attributed the increase, in large part, to the lower cocaine testing cutoff levels implemented as a result of the

2008 HHS Guidelines (Quest, 2012). In the same report, Quest also noted that amphetamines positives rose by nearly 26 percent, continuing an existing upward trend, but also were “likely boosted by better detection related to the new, lower Federally-mandated cutoffs.” In comparison to the 2010 positive testing rates for Federal workplace drug testing performed by Quest, the results for 2012 indicate a 12.5 percent increase in cocaine positives and a 37 percent increase in amphetamines positives with 2013 continuing the multi-year upward trend (Quest, 2014).

As detailed in the NRC report, “Summary of Fitness for Duty Performance Reports for Calendar Year 2013,” an adverse trend in the commercial nuclear industry had been observed over the prior 5 years associated with the year-over-year increases in amphetamines¹ positive test results (see table in this section). While accounting for a relatively small percentage of the total positive drug test results in 2013 at 8.9 percent, amphetamines positives have continued to grow in comparison to previous years. For example, the share of amphetamines positives, as a percentage of all positive drug test results in 2013

(8.9 percent), is 2.3 times higher than the percentage in 2009 (3.9 percent). Viewed another way, the percentage of individuals testing positive for amphetamines has trended upward since 2009. In 2009, 0.023 percent of individuals tested positive for amphetamines; by 2013, the positive rate increased to 0.052 percent. Conversely, cocaine use as a percentage of all positives has declined by 15.9 percent from 1990 (the first year of 10 CFR part 26 drug testing) to 2013. While cocaine use has trended downward, it continues to be the third most detected substance, accounting for 13.2 percent of positive drug test results in 2013.

TRENDS IN AMPHETAMINES AND COCAINE USE

Substance	1990 (percent)	2009 (percent)	2010 (percent)	2011 (percent)	2012 (percent)	2013 (percent)	Change (1990–2013) (percent)
Amphetamines	2.8	3.9	5.7	8.3	6.2	8.9	6.1
Cocaine	29.0	16.2	13.1	12.4	12.9	13.2	– 15.9

Notes: 1. The positive testing percentages are calculated by taking the total number of positives for the particular substance and dividing that figure by the total number of positive drug test results in the year.

2. Data from 1990, the first year of testing under 10 CFR part 26, are included as the baseline for comparison.

While most of the proposed changes in this rulemaking would be made to better align 10 CFR part 26 with the 2008 HHS Guidelines, some are based on lessons learned during the implementation of the 2008 FFD final rule by licensees and other entities. In particular, the NRC is proposing a number of changes that would enhance the ability of licensees and other entities to identify individuals attempting to subvert the drug testing process.

Beginning in 2009, licensees and other entities had the option to use electronic reporting forms (e-forms) created by the NRC, in collaboration with licensees and other entities, in order to meet the annual FFD drug and alcohol testing program reporting requirements in § 26.717, “Fitness-for-duty program performance data” and § 26.417(b)(2). These e-forms² provide a uniform way of reporting detailed information on each drug and alcohol testing violation, and their use by licensees and other entities has continued to grow (from over 80 percent in 2011 to 93 percent in 2013).

Analysis of FFD program performance data from 2011 through 2014 identified a significant new trend: The prevalence of subversion attempts of the drug testing process. In 2011, over 13.2 percent of the total testing violations were donor subversion attempts (143 of

1,080 testing violations), with even more subversion attempts in subsequent years: 15.9 percent in 2012 (177 of 1,114 testing violations), 14.7 percent in 2013 (148 of 1,007 violations), and 16.5 percent in 2014 (187 of 1,133 testing violations). If the number of alcohol positive testing violations is removed from the total testing violations each year, the percentage of drug testing violations determined to be subversion attempts increases to 17.5 percent in 2011, 20.6 percent in 2012, 19.2 percent in 2013, and 21.3 percent in 2014. An attempt to subvert the testing process demonstrates a lack of integrity and honesty and a willful act to refuse to comply with an NRC-required drug test (see 10 CFR 26.89(c), 26.825, “Criminal penalties,” and 50.5, “Deliberate misconduct”). Consequently, drug-using individuals present a safety vulnerability because of the potential for human performance issues due to drug use. Drug-using individuals could also present a security vulnerability because of their impairment or willful misconduct. As a result, the NRC is proposing a number of changes in this proposed rule to enhance the ability of FFD testing programs to detect individuals attempting to subvert the drug testing process.

Stakeholder outreach on the proposed rule is described in Section III.B of this

document. The basis for each proposed change is discussed in Section III.C of this document. The regulatory basis for this proposed rule, issued on May 10, 2013, provides further discussion on the technical merits of this rulemaking.

2. Societal Drug Use

As described in the President’s 2014 “National Drug Control Strategy,” societal use of legal and illegal drugs and substances continues to evolve and affects every sector of society. The prevalence of drug use in society is also documented in the “Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health” (NSDUH), an annual survey sponsored by SAMHSA. This survey is the primary source of information on the use of illegal drugs, alcohol, and tobacco in the civilian, non-institutionalized population in the United States, ages 12 and older. The NSDUH survey estimated that in 2014, 10.2 percent of the U.S. population aged 12 or older (approximately 27.0 million Americans) used an illegal drug in the past month. This estimate was based on the number of individuals surveyed that reported using an illegal drug during the month prior to participating in the NSDUH survey interview. Among adults aged 26 or older, those potentially in the U.S. workforce, the rate of illegal drug

¹ Initial drug testing for amphetamines and confirmatory drug testing for amphetamine and methamphetamine is required by 10 CFR part 26.

² The NRC FFD electronic forms are available for review at the following NRC website: <https://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/submit-ffd-reports.html>.

www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/submit-ffd-reports.html.

use was 8.3 percent, representing an upward trend since 2002. Although SAMHSA attributes this increase to marijuana use, it demonstrates the prevalence of illegal drug use in the workforce. Societal drug use presents a continual challenge to the fitness of the workforce relied on by licensees and other entities to perform safety and security significant duties, with the result that potential impairment and the adverse impact on human performance may affect public health and safety.

B. Public Input Regarding Proposed Revisions to 10 CFR Part 26 To Include Aspects of the 2008 Health and Human Services Guidelines

After HHS issued the 2008 HHS Guidelines, the NRC performed a comprehensive review of 10 CFR part 26 and the 2008 HHS Guidelines to identify provisions in the NRC's regulations that may need to be revised. Two public meetings were held in 2009, on February 24 and June 24, with regulated entities, interest groups, and members of the general public to discuss the changes in the 2008 HHS Guidelines. In 2010, the NRC analyzed the DOT's final rule changes to 49 CFR part 40, "Procedures for Transportation Workplace Drug and Alcohol Testing Programs" (75 FR 49850; August 16, 2010) to understand how another Federal agency that tests civilians implemented the 2008 HHS Guidelines. The NRC also analyzed lessons learned from implementation of the 2008 FFD final rule. Collectively, these efforts resulted in a list of potential changes to 10 CFR part 26 that the NRC presented, for feedback, at a third public meeting held on October 11, 2011. The NRC summarized public comments received at the October 11 meeting, as well as emailed comments received subsequent to the meeting, in a document titled "Comments for the October 11, 2011, Public Meeting" (included as Enclosure 3 in package available via ADAMS Accession No. ML112930153). A fourth meeting was held on September 11, 2013, to inform the public of the status of the rulemaking. Public meetings were attended by representatives of nuclear power plant licensees, the Nuclear Energy Institute, the Institute of Nuclear Power Operations, the International Brotherhood of Electrical Workers, and HHS.

Based upon feedback received during the four public meetings, some of the NRC-proposed revisions were removed from consideration because the NRC decided that it was not appropriate to pursue those particular issues in this rulemaking, while others were revised. The NRC-proposed revisions, along with

associated issues raised by the public, are discussed in Section III.C of this document.

C. Description of Proposed Changes

This section includes a description of each proposed change, the rationale for each change, and a discussion of public comments that informed the NRC's development of the changes.

Definitions

During the October 11, 2011, public meeting, an industry participant requested that the NRC review the use of certain terms under 10 CFR part 26 for consistency with the 2008 HHS Guidelines. The NRC performed a review and proposes to add seven new definitions and revise seven existing definitions under § 26.5, "Definitions." The revisions and additions would improve consistency with Section 1.5 of the 2008 HHS Guidelines and would improve the clarity, consistency, and accuracy of the requirements under 10 CFR part 26. Specifically, the following definitions would be added: *Cancelled test*, *carryover*, *Certifying Scientist*, *Federal custody and control form*, *lot*, *rejected for testing*, and *Responsible Person*. The following definitions would be revised: *calibrator*, *control*, *dilute specimen*, *HHS-certified laboratory*, *invalid result*, *limit of quantitation*, and *substituted specimen*.

Cancelled test. The MRO will cancel the testing of a donor's urine specimen and report that action to the licensee or other entity after the testing laboratory (*i.e.*, licensee testing facility (LTF) or HHS-certified laboratory) reports that the specimen was rejected for testing or the donor requested additional testing of a specimen at a second HHS-certified laboratory under § 26.165(b) and the specimen was not available for testing due to circumstances outside of the donor's control (*e.g.*, specimen is lost in transit). Sections 26.129(b)(2) and 26.159(b)(2) describe the only circumstances requiring an MRO to "cancel the testing of a donor's urine specimen." However, §§ 26.129(b)(2) and 26.159(b)(2) do not use the term *cancelled test*, nor is the term defined under § 26.5. Adding the definition for *cancelled test* and updating §§ 26.129(b)(2) and 26.159(b)(2) to specifically use that term would clarify the actions taken by an MRO and improve consistency between 10 CFR part 26 and the 2008 HHS Guidelines. The NRC is also proposing to add the term *cancelled test* to § 26.165(f)(1) and (f)(2) to clarify the actions taken by an MRO when a specimen is rejected for testing by the laboratory and the MRO cancels the testing of the specimen. For

completeness, a *cancelled test* for alcohol breath testing is also defined. The definition presented by the NRC staff at the October 11, 2011, public meeting only described cancelled test results associated with urine testing. For alcohol testing only, *cancelled test* means a test result that was not acceptable because testing did not meet the quality assurance and quality control requirements in § 26.91.

Carryover. The proposed rule would add a definition for *carryover* to § 26.5. *Carryover* is the effect that occurs when a test result for a donor's specimen or quality control sample has been affected by a preceding specimen tested on the same analytical instrument. For example, if the concentration of a drug in one donor specimen was not completely eliminated from the analytical instrument before the next donor specimen is tested, the residual drug concentration in the instrument may contribute to a false positive test result for the next donor specimen tested. *Carryover* would also apply to donor specimens containing an adulterant or interfering substance. The term *carryover* is not currently defined under § 26.5. However, the term *carryover* is used in §§ 26.137(e)(7) and 26.167(a), which require LTFs and HHS-certified laboratories to ensure that *carryover* does not contaminate the testing of a donor's specimen or otherwise affect a donor's specimen results. In addition, § 26.91(c)(5) describes the requirement to ensure that *carryover* does not affect alcohol testing results when using evidential breath testing devices. The NRC's proposed definition is similar to the definition in Section 1.5 of the 2008 HHS Guidelines but does not include the phrase "(*e.g.*, drug concentration)" because *carryover* applies also to validity testing (*e.g.*, adulterants, interfering substances) and alcohol testing.

Certifying Scientist. The proposed rule would add a definition for *Certifying Scientist* to § 26.5. The position title is used in § 26.169(a) and (g) but is not currently defined. A *Certifying Scientist* would be defined as the individual at the HHS-certified laboratory responsible for verifying the chain of custody and scientific reliability of any test result reported by the HHS-certified laboratory. Adding this definition would improve consistency between 10 CFR part 26 and the 2008 HHS Guidelines. A conforming change would be made to § 26.169(a) to capitalize the position title in the phrase "the laboratory's certifying scientist."

Federal custody and control form (Federal CCF). The proposed rule would add a definition for the term *Federal*

custody and control form (Federal CCF) to § 26.5. The Federal CCF is defined as any HHS-approved form, which has not expired, that is published in the **Federal Register** and is used to document the collection, custody, transport, and testing of a specimen. Including this definition would align 10 CFR part 26 with Section 1.5 of the 2008 HHS Guidelines and improve the clarity of the rule by defining the term, which is already used in § 26.153(g). The proposed rule would revise the NRC's initial proposed definition of *Federal CCF*, based on feedback received during the October 11, 2011, public meeting. The definition that the NRC proposed at that meeting listed the specific name of the HHS-approved form used for urine drug testing (*i.e.*, Federal Drug Testing Custody and Control Form) and closely paralleled the definition in Section 1.5 of the 2008 HHS Guidelines. However, based on comments received during the meeting, the NRC agrees that referencing the specific name on the form was too prescriptive and could require additional revision to 10 CFR part 26, should HHS revise the form name in the future. Therefore, the NRC is proposing to use the generic title, *Federal CCF*, to avoid the need for future regulatory changes, should the title of the form change. The definition may also provide flexibility in accounting for additional forms that SAMHSA may create for use when conducting drug and validity testing of alternative specimens (*e.g.*, oral fluids, hair). To align with the new definition, "Federal custody-and-control form," which appears in § 26.153(g), would be replaced with the term "*Federal CCF*." In addition, to improve the consistency of terminology used throughout 10 CFR part 26, the NRC is also proposing to replace the term "custody and control form" with the term "*Federal CCF*." The plural versions, "custody and control forms" and "custody and control form(s)," would also be replaced with the terms "Federal CCFs" and "Federal CCF(s)," respectively. Finally, the proposed rule would correct inconsistencies where "custody-and-control" form or forms were used incorrectly and instead should have referred to "chain of custody" form or forms.

The NRC's regulations under 10 CFR part 26 do not preclude the use of electronic versions of the Federal CCF or the use of licensee or other entity-developed forms, consistent with existing requirements in § 26.153(g). The NRC supports the use of technological advancements to improve the quality of information included on the Federal CCF (*e.g.*, legibility,

accuracy, and completeness of information); reduce undue delays and/or the canceling of specimen tests due to paperwork irregularities; facilitate timely transmission of information to and from collectors, laboratories, and responsible licensee representatives (*e.g.*, the MRO); and reduce recordkeeping and reporting costs.

Lot. The proposed rule would add a definition for *lot* to § 26.5, representing units that have the same starting materials, performance characteristics, and expiration date. The term is used in 10 CFR part 26 but is not currently defined. Adding this definition would improve consistency between 10 CFR part 26 and the definition of *lot* in Section 1.5 of the 2008 HHS Guidelines. The proposed rule would use the same definition in the 2008 HHS Guidelines by defining *lot* as a number of units of an item manufactured from the same starting materials within a specified period of time for which the manufacturer states that the items have essentially the same performance characteristics and the same expiration date. The proposed rule also would include in the definition the parenthetical statement from the 2008 HHS Guidelines definition that provides examples of the term "item." The NRC would change one of the examples in the parenthetical statement by replacing "quality control material" with "quality control samples." The term "quality control material" has not been used in 10 CFR part 26.

Rejected for testing. The proposed rule would add to § 26.5 a definition for *rejected for testing* that is similar to the definition in Section 1.5 of the 2008 HHS Guidelines, referring to a report by a licensee testing facility or HHS-certified laboratory that no tests can be performed on a specimen. The term *rejected for testing* appears in § 26.169(h)(8) but is not currently defined. Including a definition would clarify what information is being reported by the HHS-certified laboratory to the licensee or other entity in the annual quantitative summary of test results. In addition, defining the term would align with two additional proposed changes to §§ 26.129(b)(1)(ii) and 26.159(b)(1)(ii), clarifying the existing step that an LTF or HHS-certified laboratory would take, if a licensee or other entity had reason to question the integrity and identity of a specimen (*i.e.*, reject the specimen for testing). In § 26.129(b)(1)(ii), the phrase "the specimen may not be tested" would be replaced with the phrase "the licensee testing facility shall reject the specimen for testing." In § 26.159(b)(1)(ii), the phrase "the

specimens may not be tested" would be replaced with the phrase "the laboratory shall reject the specimens for testing." Improving the consistency of terminology used when a specimen cannot be tested improves the regulatory efficiency of 10 CFR part 26.

Responsible Person. The proposed rule would add a definition for *Responsible Person* to § 26.5. The position title is used in § 26.31(d)(1)(D) but is not currently defined. A *Responsible Person* would be defined as the person at the HHS-certified laboratory who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory. Adding this definition would improve consistency between 10 CFR part 26 and the 2008 HHS Guidelines. A conforming change would be made to § 26.167(f)(3) to capitalize the position title in the phrase "a statement by the laboratory's responsible person."

Calibrator. The proposed rule would revise the definition for *calibrator* in § 26.5 to more closely align with the definition in Section 1.5 of the 2008 HHS Guidelines and to also improve internal consistency of terminology used in 10 CFR part 26. The definition of *calibrator* would be revised to include a clarifying statement that a calibrator is a solution of known concentration "in the appropriate matrix" that aligns with the definition in the 2008 HHS Guidelines. The phrase "test specimen/sample" would be replaced with the phrase "donor specimen or quality control sample" to improve consistency with the terminology used in 10 CFR part 26. The last sentence of the definition, which states that "calibrators may be used to establish a cutoff concentration and/or a calibration curve over a range of interest," would be deleted. Although a part of this sentence aligns with the 2008 HHS Guidelines, the sentence is not a definition, but rather a voluntary provision that a laboratory may use a calibrator to establish a calibration curve. The determination of calibration curves is an internal laboratory process that already must be described in standard operating procedures for LTFs in § 26.127, "Procedures," and is evaluated during NLCP inspection of HHS-certified laboratories.

Control. The proposed rule would revise the definition of *control* in § 26.5 to conform to the definition of the term in Section 1.5 of the 2008 HHS Guidelines. The term *control* in § 26.5 would be revised by replacing the phrase "a sample used to monitor the status of an analysis to maintain its

performance within predefined limits” with the phrase “a sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.”

Dilute specimen. The proposed rule would revise the definition of *dilute specimen* in § 26.5 to conform to the definition of the term in Section 1.5 of the 2008 HHS Guidelines. The phrase “concentrations that are lower than expected for human urine” would be revised to read as “values that are lower than expected but are still within the physiologically producible ranges of human urine.” The current definition incorrectly references “concentrations” which does not apply to a specific gravity reading. The current definition also does not clearly state that creatinine and specific gravity measurements in a dilute specimen are still within the range that could be produced by a human being.

HHS-certified laboratory. The current definition of an *HHS-certified laboratory* in § 26.5 lists the **Federal Register** citations for each final version of the HHS Guidelines (originally published in 1988, and amended in 1994, 1998, and 2004). Under this definition, an HHS-certified laboratory must meet the 2004 HHS Guidelines, which were published on April 13, 2004 (69 FR 19643). No laboratory performing testing for 10 CFR part 26 licensees or other entities currently meets this definition because the definition refers to the superseded 2004 HHS Guidelines; rather, HHS certifies laboratories to the HHS Guidelines that are in effect. The proposed rule would correct this restriction by defining an *HHS-certified laboratory* as a laboratory that is certified to meet the standards of the HHS Guidelines at the time that drug and validity testing of a specimen is performed for a licensee or other entity. Other requirements in 10 CFR part 26 already specify the drug testing panel and testing cutoff levels, validity testing requirements, and quality control requirements. The proposed change to the definition of *HHS-certified laboratory* would eliminate the need to revise 10 CFR part 26, should future versions of the HHS Guidelines be published. Two conforming changes would also be made, based on the revision to the definition of *HHS-certified laboratory*. The first change would revise §§ 26.4(j)(3) and 26.153(a) to reference “HHS-certified laboratories as defined in § 26.5.” Section 26.153(a) would also be revised to remove the reference to the physical address of the Division of Workplace Programs as the location to obtain information

concerning the certification status of laboratories.

Invalid result. The proposed rule would revise the definition of *invalid result* in § 26.5 to be consistent with the definition of the term in Section 1.5 of the 2008 HHS Guidelines and would also improve the clarity and accuracy of the 10 CFR part 26 rule. The phrase “for a specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, contains inconsistent physiological constituents, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result” would be replaced with “in accordance with the criteria established in § 26.161(f) when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test.” The revised definition would also correct an inaccuracy in the current definition of *invalid result*, which does not include “specimen validity test.”

Limit of Quantitation. The proposed rule would revise the definition for *Limit of Quantitation (LOQ)* in § 26.5 to more closely align with Section 1.5 of the 2008 HHS Guidelines. To align with the terminology used in 10 CFR part 26, the proposed definition would use “analyte” instead of the word “measurand.”³

Substituted specimen. The proposed rule would revise the definition of *substituted specimen* in § 26.5 to align with the definition of the term in Section 1.5 of the 2008 HHS Guidelines. The phrase “specimen with creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human physiology” would be replaced with “a specimen that has been submitted in place of the donor’s urine, as evidenced by creatinine and specific gravity values that are outside the physiologically producible ranges of human urine.”⁴ The revision would also improve the clarity of the rule by explaining that a substituted specimen is the result of donor action to subvert the testing process by stating that the specimen “has been submitted in place of the donor’s urine.”

³ “Analyte” means the drug or drug metabolite measured by an initial or confirmatory drug test.

⁴ “Creatinine” means a substance that is created in a human being as a result of muscle metabolism and is excreted in urine. The creatinine concentration of each urine specimen is measured by validity testing.

Drug Testing Panel Additions

The proposed rule would add two amphetamine-based chemical compounds: Methylenedioxyamphetamine (MDMA) and methylenedioxyamphetamine (MDA) to the NRC-required drug testing panel, consistent with the drug testing panel in Section 3.4 of the 2008 HHS Guidelines. The 2008 HHS Guidelines also added an additional amphetamine-based chemical compound, methylenedioxyethylamphetamine (MDEA); however, in its 2017 mandatory guidelines (82 FR 7920; January 23, 2017) HHS subsequently removed MDEA from its drug testing panel because HHS determined that the number of positive MDEA specimens reported from its certified laboratories does not support testing specimens for MDEA. MDMA (also known as Ecstasy or Molly) and MDA are listed in Schedule I of the Schedules of Controlled Substances (21 CFR 1308.11). A Schedule I drug or substance has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks an accepted safety for use of the drug or substance under medical supervision (21 U.S.C. 812 (2012)). The proposed rule would revise §§ 26.31(d)(1) and 26.405(d) to identify MDMA and MDA as substances for which licensees and other entities are required to test; § 26.133, “Cutoff levels for drugs and drug metabolites,” and § 26.163(a)(1) to require initial testing for MDMA and MDA; and § 26.163(b)(1) to require confirmatory testing for MDMA and MDA. By requiring licensees and other entities to test for additional substances, a greater range of drugs that impair human performance can be detected. Also, it would assist in the identification of those persons who, because they use illegal drugs, exhibit characteristics of not being trustworthy and reliable. The drugs MDMA and MDA would be added to the NRC-required drug testing panel because of their potential adverse effects on human performance, which were detailed by the HHS in the notice of proposed revisions to the HHS Guidelines, published in the **Federal Register** on April 13, 2004 (69 FR 19673).

The proposed rule would also expand the NRC-required drug testing panel to include initial testing for 6-AM, consistent with Section 3.4 of the 2008 HHS Guidelines. This change would improve the assurance that the testing method used under 10 CFR part 26 would identify an individual using heroin, a Schedule I drug. Currently, 10

CFR part 26 only permits the testing of a specimen for 6-AM when the specimen also tests positive for morphine (*i.e.*, the morphine concentration is greater than the confirmatory testing cutoff level). The HHS implemented initial testing for 6-AM in the 2008 HHS Guidelines based on the analysis of laboratory testing data that demonstrated that 6-AM was detectable in the specimens of some individuals even when the specimens tested negative for morphine.

Revised Initial Drug Testing Cutoff Levels

The 2008 HHS Guidelines established the scientific and technical bases for lowering the initial drug testing cutoff levels for amphetamines and cocaine metabolites. The proposed rule would update the substances and cutoff levels for initial drug testing, as listed in the tables in §§ 26.133 and 26.163(a)(1), to conform with Section 3.4 of the 2008 HHS Guidelines. Specifically, the proposed rule would make the following changes in each table: (1) Lower the initial test cutoff level for amphetamines (abbreviated in the tables as AMP), (2) lower the initial test cutoff level for cocaine metabolites, (3) clarify the existing testing requirement for “opiate metabolites” by replacing the term with “codeine/morphine,” (4) include a new footnote 1 to each table to clarify that the target analyte for “codeine/morphine” testing is morphine, (5) clarify in a new footnote 2 to each table that either a single or multiple initial test kit(s) may be used for amphetamines testing, and (6) include a new footnote 3 in each table to clarify that methamphetamine (abbreviated in the tables as MAMP) is the target analyte for amphetamines and methamphetamine testing. The column header “Drug or metabolites” in the tables in §§ 26.133 and 26.163(b)(1) would also be revised to “Drugs or drug metabolites” to align with the table titles.

Lowering the cutoff levels for these existing drugs and drug metabolites in the NRC-required testing panel would increase the timeframe (*i.e.*, the window of detection) in which these drugs can be detected in an individual’s urine after use and may also lead to improved deterrence. Increasing the window of detection for these substances would provide a higher degree of assurance that persons who are using illegal drugs or misusing legal drugs would be identified. The NRC anticipates that the proposed lower testing cutoff levels would increase the number of urine specimens identified as containing amphetamine, cocaine metabolite, and

methamphetamine. These anticipated outcomes are based on increases in detection reported by Federal employee workplace drug testing programs and the DOT testing program subsequent to implementing the lower testing cutoff levels in the 2008 HHS Guidelines, as discussed in the regulatory basis and the regulatory analysis for this proposed rule.

In addition, the proposed rule would revise §§ 26.133 and 26.163(a)(1) to clarify that the specified testing cutoff levels are used by an LTF or an HHS-certified laboratory to determine whether a specimen is either “negative” or “positive” for each drug or drug metabolite being tested. This change better aligns 10 CFR part 26 with Section 11.19(b) and (c) of the 2008 HHS Guidelines, which require the HHS-certified laboratory to make a determination that each specimen is either “negative” or “positive,” respectively, for each drug and drug metabolite tested.

Revised Confirmatory Drug Testing Cutoff Levels

The 2008 HHS Guidelines established the scientific and technical bases to justify lowering the confirmatory drug testing cutoff levels for amphetamine, cocaine metabolite, and methamphetamine and expanding the testing panel to include confirmatory drug testing for the Ecstasy drugs MDMA and MDA. The NRC proposes to expand the number of substances in the NRC-required testing panel and to lower the cutoff levels for confirmatory drug tests, as listed in the table in § 26.163(b)(1), to align with Section 3.4 of the 2008 HHS Guidelines. Specifically, the proposed rule would make the following changes: (1) Lower the confirmatory test cutoff level for amphetamine from 500 ng/mL⁵ to 250 ng/mL; (2) lower the confirmatory test cutoff level for cocaine metabolite from 150 ng/mL to 100 ng/mL; (3) lower the confirmatory test cutoff level for methamphetamine from 500 ng/mL to 250 ng/mL; (4) eliminate table footnote 3, which specified the requirement that confirmatory testing of 6-AM only proceed when confirmatory testing shows a morphine concentration exceeding 2000 ng/mL; (5) redesignate table footnote 4 as footnote 3 and update the text to lower the amphetamine concentration from 200 ng/mL to 100 ng/mL that must also be present in a specimen to be positive for methamphetamine; and (6) include confirmatory testing for MDMA and

MDA at a cutoff level of 250 ng/mL. Similar to the changes made to the initial testing cutoff levels, lowering the confirmatory testing cutoff levels for amphetamine, cocaine metabolite, and methamphetamine would increase the timeframe in which these drugs can be detected in an individual’s urine after use and may also add to the deterrent effect of the rule. In addition, the proposed rule would make two clarifying changes to the table in § 26.163(b)(1) by revising the term “Opiates” to “Opiate metabolites” and adding the abbreviation “(6-AM)” after 6-acetylmorphine. Finally, the column header “Drug or metabolites” in the table in § 26.163(b)(1) would be revised to “Drugs or drug metabolites” to align with the table title. These changes would improve consistency with Section 3.4 of the 2008 HHS Guidelines and with the proposed revisions to §§ 26.133 and 26.163(a)(1).

The proposed rule would update the information that each HHS-certified laboratory must include in the annual statistical summary report of test results provided to each licensee or other entity under § 26.169(h)(3) to reflect the expanded drug testing panel in revised §§ 26.31(d)(1) and 26.405. Specifically, the proposed rule would require each HHS-certified laboratory to include, in the annual statistical summary of urinalysis testing provided to each licensee and other entity, the number of specimens reported as positive for MDMA and MDA. Additional conforming changes would improve the clarity and uniformity of the names of the drugs and drug metabolites listed in § 26.169(h)(3), to include adding “(as THCA)”⁶ after “Marijuana metabolites,” adding “(as benzoylecgonine)” after “Cocaine metabolite,” revising “6-AM” to “6-acetylmorphine (6-AM),” and revising “Phencyclidine” to “Phencyclidine (PCP).”

Validity Testing of Adulterants at HHS-Certified Laboratories

The proposed rule would revise the decision point used in the validity tests performed by HHS-certified laboratories, as described in § 26.161(c)(3) through (c)(6) and § 26.161(f)(5) and (f)(7), by replacing the limit of detection (LOD) with the limit of quantitation (LOQ) as the decision point for determining if a specimen contains an adulterant (*i.e.*, adulterated test result) or the possible presence of an adulterant (*i.e.*, invalid test result). The difference between the LOD and the LOQ for a testing assay is the ability to

⁵ The unit ng/mL is nanograms per milliliter or a millionth of a gram per liter.

⁶ THCA is an abbreviation for delta-9-tetrahydrocannabinol-9-carboxylic acid.

reliably quantify the analyte. At the LOD, the validity test must meet all HHS-certified laboratory criteria for result acceptance, except quantitation. At the LOQ, the validity test must reliably confirm the presence of the analyte, reliably quantify the concentration of the analyte, and meet all HHS-certified laboratory criteria for result acceptance. Use of the LOQ provides an additional donor protection on the accuracy of validity testing (*i.e.*, in making the conclusion that results are adulterated or invalid).

The proposed changes to § 26.161(c)(3) through (c)(6) are consistent with Section 3.5 of the 2008 HHS Guidelines, which describes the validity testing criteria for the adulterants chromium (VI), halogens (*e.g.*, bleach, iodine, fluoride), glutaraldehyde, and pyridine (pyridinium chlorochromate). The proposed changes to § 26.161(f)(5) and (f)(7) are consistent with the validity testing criteria in Section 3.8 of the 2008 HHS Guidelines for the same adulterants described in the previous sentence but as applied to invalid results.

The NRC is not proposing to change the initial validity testing requirement in § 26.131(b)(5) that applies to LTF testing for the possible presence of halogen. Section 26.131(b)(5) currently permits an LTF to use a “halogen colorimetric test (halogen concentration equal to or greater than the limit of detection (LOD)).” The NRC is not proposing to change the use of LOD in this instance, because LTFs already must send any specimen identified with the possible presence of an adulterant to an HHS-certified laboratory for initial and confirmatory validity testing, where the LOQ of the test would be utilized.

The proposed rule would also revise § 26.161(c)(5) and (c)(6) to permit HHS-certified laboratories to conduct confirmatory validity testing for the adulterants glutaraldehyde and pyridinium chlorochromate using “a different confirmatory method (*e.g.*, gas chromatography/mass spectrometry (GC/MS))” instead of what is currently required, which is only “GC/MS for the confirmatory test.” The proposed changes would provide additional flexibility in the confirmatory testing methods that may be used by the laboratory and would align with similar testing requirements in § 26.167(e)(1), the current version of § 26.153(c) as described in the Statement of Considerations for the 2008 FFD final rule (73 FR 17091 and 17102; March 31, 2008), and Section 11.19(d) of the 2008 HHS Guidelines.

Special Analyses Testing of Urine Specimens

Special analyses testing is an NRC testing methodology introduced in the 2008 FFD final rule to address the circumstance where a donor consumes a large quantity of fluid just prior to providing a urine specimen for testing in the hope of diluting the concentration of any drugs and drug metabolites in the specimen below the standard testing cutoff levels to avoid detection (*i.e.*, to produce a negative drug test result). This testing methodology is not included in the HHS Guidelines but provides licensees and other entities with an added level of assurance that an individual with a dilute specimen is not attempting to hide drug use. Section 26.163(a)(2) currently provides each licensee and other entity with the option to require the HHS-certified laboratory to conduct special analyses of dilute specimens (*i.e.*, conduct confirmatory testing to the LOD for drugs and drug metabolites when the immunoassay response of the initial drug test is equal to or greater than 50 percent of the cutoff calibrator). For example, if a specimen is dilute and the initial test for marijuana metabolites measured a concentration of 25 ng/mL (the initial cutoff level for marijuana metabolites is 50 ng/mL), special analyses testing would then be performed on the specimen. Using a lower cutoff level for the testing of dilute specimens enhances the ability of licensees and other entities to identify drug-using individuals attempting to avoid detection through the consumption of large quantities of fluid just prior to providing a specimen for testing. The proposed rule would make four changes to the special analyses testing requirements in § 26.163(a)(2).

First, the proposed rule would require all licensees and other entities to conduct special analyses testing of dilute specimens. An analysis of the NRC’s FFD program performance reports for calendar years 2011 through 2014 demonstrates the effectiveness of special analyses testing because these data show that additional positive results were identified for pre-access, random, and post-event special analyses tests. As of 2014, 92 percent of licensees and other entities have adopted the special analyses testing policy. The proposed rule would eliminate references to the option for licensees and other entities to conduct special analyses testing of specimens with dilute validity test results that appear in §§ 26.31(d)(1)(ii); 26.163(a)(1) and (b)(1); 26.183(c), (c)(1), and (d)(2)(ii); and

26.185(g)(2) and (g)(3). These tests would instead be required.

Second, the proposed rule would lower the immunoassay percentage response for initial testing in § 26.163(a)(2)(ii) that HHS-certified laboratories must use to determine if special analyses testing is to be conducted. The proposed rule would lower the immunoassay response from “equal to or greater than 50 percent of the cutoff calibrator” to “equal to or greater than 40 percent of the cutoff calibrator.” Use of a lower cutoff level to evaluate the immunoassay response could increase the number of specimens subject to special analyses testing and would improve the ability of licensees and other entities to identify drug-using individuals attempting to subvert the drug testing process. This change would not affect the drug testing assays used by HHS-certified laboratories because under the 2008 HHS Guidelines, each laboratory must already validate the accuracy of each assay to 40 percent of the cutoff calibrator. Laboratories would need to change their administrative procedures to define the initial test result concentration that would trigger special analyses testing.

Third, the proposed rule would replace the LOD with the LOQ as the confirmatory drug testing cutoff level to be used by HHS-certified laboratories when conducting special analyses testing. Currently, § 26.163(a)(2)(ii) requires the use of the LOD as the cutoff level for special analyses testing of dilute specimens. The difference between the LOD and the LOQ for a drug testing assay is the ability to reliably quantify the analyte. At the LOD, the confirmatory drug test must meet all HHS-certified laboratory criteria for result acceptance except quantitation. At the LOQ, the confirmatory drug test must reliably confirm the presence of the analyte, reliably quantify the concentration of the analyte, and meet all HHS-certified laboratory criteria for result acceptance. The LOQ provides an additional donor protection on the accuracy of special analyses test results. To receive and maintain laboratory certification by the NLCP, HHS-certified laboratories must already determine both the LOD and LOQ for each drug testing assay. Therefore, changing the decision point from the LOD to the LOQ for reporting confirmatory drug test results would not require laboratories to change the testing assays used.

The NLCP also requires all HHS-certified laboratories to validate the accuracy and precision of each confirmatory drug test at or below 40 percent of the cutoff. To meet this

testing specification, the laboratory must establish both the LOD and the LOQ below the 40 percent cutoff, which results in variability amongst laboratories on how far below the 40 percent cutoff the LOD and LOQ are established. This is dependent, in part, on the instrumentation and testing processes used at the laboratory. The NRC acknowledges this variability. Some attendees at the public meetings requested a standardized level be used across all laboratories performing special analyses testing. However, this position would be contrary to the 10 CFR part 26 regulatory framework that enables licensees and other entities to use lower cutoff levels in the testing for drugs and drug metabolites, as permitted under § 26.31(d)(3)(iii).

Fourth, the proposed rule would expand the special analyses testing requirement in § 26.163(a)(2)(i) to include the testing of some specimens collected under direct observation. Section 26.115(a) describes the exclusive grounds for performing a directly observed collection. Under the current rule, a directly observed collection may be performed when sufficient information has been obtained during the collection process or in the testing of a previous specimen to indicate a possible subversion attempt by the donor or when an individual has a confirmed positive drug test result on a prior occasion. As such, a directly observed collection after either of these circumstances provides additional assurance that the subsequent specimen obtained for testing came directly from the donor's body and was not altered to avoid detection of drug use. Likewise, special analyses testing would provide additional assurance that drugs and drug metabolites present in the specimen collected under direct observation from a donor would be identified, which would improve the MRO's ability to determine whether a subversion attempt was made on the initial specimen collected from the donor. For example, an initial unobserved specimen provided by a donor is determined by the collector to be out of the acceptable temperature range specified in § 26.111(a) and tests negative for drugs, and the second specimen collected under direct observation from the donor tests positive for a drug. In this example, the differences in test results from the initial and second specimen collected provides conclusive evidence to the MRO to make a subversion determination on the initial specimen provided. Therefore, the proposed rule would revise § 26.163(a)(2)(i) to require

that special analyses testing be performed on specimens collected under § 26.115(a)(1) through (a)(3), and (a)(5).

Section 26.115(a)(1) describes the situation where a donor has presented a specimen that has been reported by an HHS-certified laboratory as adulterated, substituted, or invalid, and the MRO determines that no adequate medical explanation exists for the result and that another specimen should be collected from the donor. An analysis of the NRC's FFD program performance reports for calendar years 2011 through 2014 identified subversion attempts where the HHS-certified laboratory reported an invalid test result for the initial specimen provided by the donor and either the donor refused to provide a second specimen under direct observation or the second specimen collected under direct observation tested positive for a drug. Use of special analyses testing on the second specimen collected would provide additional assurance that drug use would be detected because a period of days would lapse from the point of collection of the initial specimen, testing of that specimen at a laboratory, MRO review of the test results and discussion with the donor, MRO determination that a second specimen should be collected, and the donor appearance at a collection site to provide a second specimen under direct observation.

Section 26.115(a)(2) describes the situation where a donor provides a specimen that falls out of the acceptable temperature range specified in § 26.111(a). Section 26.115(a)(3) describes the situation where donor conduct during the collection process indicates an attempt to dilute, substitute, or adulterate the specimen. An analysis of the NRC's FFD program performance reports for calendar years 2011 through 2014 demonstrates that the majority of subversion attempts are identified based on information obtained during the specimen collection process by the collector (e.g., specimen temperature) and the collection of a second specimen from the donor under direct observation. Use of special analyses testing in these two instances would provide additional assurance that drug use would be detected in the second specimen collected under direct observation because the information from the initial collection process indicated a possible subversion attempt.

Section 26.115(a)(5) addresses the situation where the MRO verifies that a specimen is positive, adulterated, or substituted; the donor requests that a retest of the specimen be performed at a second HHS-certified laboratory; but

the specimen is not available for testing. As a result, the confirmed test result from the initial testing laboratory must be cancelled by the MRO because the donor was not afforded the opportunity to verify the test results through additional testing at a second HHS-certified laboratory. Use of special analyses testing in this instance would provide additional assurance for the same reason described for specimens collected under § 26.115(a)(1).

The proposed change to require special analyses testing of specimens collected under direct observation would require licensees and other entities to establish an approach for the licensee or other entity to use when notifying a laboratory that special analyses testing is required for a specimen.

Alternative Specimen Collection Sites

Sections 26.4(e)(6)(iv) and 26.31(b)(2) include the statement that "licensees and other entities may rely on a local hospital or other organization that meets the requirements of 49 CFR part 40, 'Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs' (65 FR 41944; August 9, 2001)." Section 26.415(c) also includes a statement that licensees and other entities need not audit "the specimen collection and alcohol testing services that meet the requirements of 49 CFR part 40, 'Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs' (65 FR 41944; August 9, 2001)." The proposed rule would eliminate the **Federal Register** citation from each part 26 section because the DOT final rule found on page 41944 in the August 9, 2001, edition of the **Federal Register** no longer represents the current version of 49 CFR part 40. The intent of these provisions was to provide licensees and other entities with flexibility to utilize collection sites that meet the DOT specimen collection requirements in 49 CFR part 40. Listing the specific **Federal Register** notice of the applicable DOT final rule is not necessary because the existing requirements in §§ 26.4(e)(6)(iv), 26.31(b)(2), 26.405(e), and 26.415(c) already specify that the local hospital or other organization must meet the requirements in 49 CFR part 40.

Specimen Collection Procedures

The proposed rule would make a number of revisions to the specimen collection procedures in 10 CFR part 26: (1) Clarify and enhance the instructions on conducting an observed collection, (2) permit the use of mirrors to assist in

performing directly observed collections, (3) allow FFD program personnel to observe a donor who is in the hydration process following the donor's inability to provide a specimen of adequate volume, and (4) clarify urine specimen quantity and acceptability provisions. The revisions would improve the clarity, consistency, and flexibility of the collection procedures and to align more closely with the 2008 HHS Guidelines.

Section 26.115(e), (f), and (f)(1) through (f)(3) would be revised to improve the clarity of instruction on conducting a directly observed specimen collection, which would improve consistency with Sections 4.4(a) and 8.9 of the 2008 HHS Guidelines.

The proposed rule would remove the first sentence in § 26.115(f), which states, "If someone other than the collector is to observe the collection, the collector shall instruct the observer to follow the procedures in this paragraph." The NRC proposes to add the following sentence to the end of the existing requirements in § 26.115(e): "If the observer is not a trained collector, the collector shall, in the presence of the donor, instruct the observer on the collection procedures in paragraph (f) of this section." The proposed change would improve the clarity of the existing requirements and ensure that the donor is informed that an individual other than the collector is to observe the specimen provision and understands the procedures that must be followed to complete the specimen collection. The proposed change also incorporates feedback received at the October 11, 2011, public meeting, at which a participant suggested using the phrase "who has received instruction" instead of the phrase "who has received training," when referring to the information that is provided to a same-gender observer by the collector. "Training" implies a formal process rather than providing oral or written instructions. The NRC agrees that the commenter's proposed wording conveys a more accurate description of how the collector would convey the information regarding specimen collection to a same-gender observer. The collector would only be required to give the same-gender observer instructions, rather than formal training.

In § 26.115(f)(2), the proposed rule would add the parenthetical statement "(a mirror may be used to assist in observing the provision of the specimen only if the physical configuration of the room, stall, or private area is not sufficient to meet this direct observation requirement; the use of a video camera

to assist in the observation process is not permitted)" to the end of the existing requirement. This proposed change also incorporates stakeholder feedback at the public meeting on October 11, 2011, at which the NRC proposed to prohibit the use of mirrors and video cameras to aid an observer in conducting a directly observed specimen collection, to align with Section 8.9(b) of the 2008 HHS Guidelines. Several industry participants commented that mirrors are currently used at some collection facilities, where the configuration of the stall does not provide adequate space for the collector to directly observe the provision of a specimen from the donor's body into the specimen container. These participants suggested that if the NRC prohibited the use of a mirror to aid in the direct observation process, physical configuration changes at some collection sites would be needed.

Based on subsequent licensee and NRC inspector feedback, the NRC has concluded that the observed collection process in § 26.115(f)(1) continues to ensure that subversion paraphernalia would be identified prior to the provision of a specimen during the observed collection process and that the use of reflective mirrors, not two-way mirrors, would be acceptable. As required by § 26.115(f)(1), prior to conducting the directly observed collection, the donor already must adjust his or her clothing to expose the area between his or her waist and knees. This step ensures that no materials to subvert the testing process (e.g., a prosthetic device, a container of synthetic urine, an ampule of an oxidizing chemical, or other subversion paraphernalia) are concealed on the donor's body and could be used during the specimen collection. Subsequent to this step, the observer would then watch urine flow from the donor's body into the collection cup. To accomplish this, the collector (or same-gender observer) must be in close proximity (in the stall or room where the specimen is provided) to meet this observation requirement. The use of a reflective mirror only aids in this assurance by preventing the donor's body or the configuration of the stall or room from obstructing the collector's view of urine flowing from the donor's body directly into the specimen collection container. By observing the area where the urine leaves the body, the direct observation process ensures that the specimen provided is from the donor and ensures the integrity of the specimen collection process. As a result, the NRC is

proposing to revise § 26.115(f)(2) to permit the use of reflective mirrors.

The NRC also proposes to revise § 26.115(f)(2) to prohibit the use of video cameras to assist in visualizing the provision of a specimen under direct observation. The NRC does not consider a video camera to be an acceptable means of providing direct observation, in part, because the conversion of visible light to an electronic format, through a video camera, is not a direct observation. The use of a video camera for direct observation would be inconsistent with the intent of the rule because the collector or observer would not be in the room or stall with the donor. Further, a video feed is an incomplete source of information because it may not detail the physiological characteristics associated with a subversion attempt and also cannot guarantee the privacy of the donor beyond the individual conducting the observation.

During the public meeting on October 11, 2011, one participant requested that the NRC consider eliminating the requirement in § 26.115(f)(1) that the donor adjust his or her clothing during the observed collection process to expose the area of the donor's body from the waist to the knees. The NRC considered this request but is not proposing to eliminate this provision for three reasons. First, the purpose of directly observing the provision of a specimen is to ensure that the drug testing process is not being subverted. The NRC's collection procedure requires the donor to remove his or her clothing between the waist and knees so that the collector can identify any paraphernalia on the individual's body that may be used to subvert the testing process, such as a prosthetic device, a container of synthetic urine, or ampule of an oxidizing chemical. Second, materials used to subvert a drug test are easily available for purchase, and licensees and other entities have reported in annual performance reports required by § 26.717 that subversion attempts have been identified during the directly observed collection process. Finally, the prevalence of subversion attempts demonstrates that individuals are actively attempting to thwart the drug testing process by specimen adulteration, substitution, and dilution.

In § 26.115(f)(3), the proposed rule would replace the phrase "If the observer is not the collector, the observer may not take the collection container from the donor, but shall observe the specimen as the donor takes it to the collector," with the phrase "If the observer is not the collector, the observer may not touch or handle the

collection container but shall maintain visual contact with the specimen until the donor hands the collection container to the collector.” The proposed rule changes would improve the clarity of the existing requirement by more closely aligning with Sections 8.9(c) and (d)(2) of the 2008 HHS Guidelines and by using terminology consistent with § 26.113(b)(3).

The proposed rule would add § 26.4(g)(6) and would revise § 26.109(b)(1) to improve the efficiency of FFD programs by providing licensees and other entities with additional flexibility in the personnel who may monitor a donor during the hydration process, which is the 3-hour period of time that is initiated after a donor is unable to provide an acceptable quantity of urine during the initial specimen collection attempt, during which fluid is provided to assist the donor in providing a specimen of adequate volume. In addition to the specimen collector that initiated the specimen collection process with the donor, a staff member designated as FFD program personnel in § 26.4(g) would be allowed to monitor the donor during the hydration process in place of the original collector. All FFD program personnel must meet honesty and integrity requirements in § 26.31(b) and have familiarity with the collection facility, specimen collectors, and 10 CFR part 26 requirements sufficient to monitor the donor during the hydration process. The additional flexibility of collection monitoring provided by the rule change would enable the collector, who initiated the collection process with a donor, to complete additional specimen collections with other donors while the initial donor hydrates. Another specimen collector, who meets the requirements in § 26.85(a), could also monitor the donor in the hydration process. The proposed change could reduce the regulatory burden on FFD programs by affording licensees and other entities additional staffing options to better manage the collection process, while maintaining appropriate oversight of the collection process. If a hydration monitor or another collector is used, the original collector would be required to note the name of the individual on the Federal CCF and the hydration monitor or second collector then would maintain control of the Federal CCF during the observation process (e.g., to document the time and volume of fluid provided to the donor, to note any unusual donor behavior, and to verify that the donor is provided with 3 hours to provide a specimen). In addition, to improve the clarity of § 26.109, the NRC is also

proposing that the last sentence of § 26.109(b)(1), “The collector shall provide the donor with a separate collection container for each successive specimen,” would become the new first sentence of § 26.109(b)(2). Section 26.109(b)(1) describes the procedures for providing fluid to a donor who is in the hydration process and includes the instruction to the collector to provide a separate collection container for each successive specimen provided by the donor. The instruction to provide a separate collection container for each specimen is more appropriate in § 26.109(b)(2), which describes the provision of subsequent specimens once a donor is in the hydration process.

The proposed rule would revise § 26.89(d) in three ways. First, § 26.89(d) would be revised to clarify that a collector shall conduct only one collection procedure at any given time, except in the instance when another collector who meets the requirements in § 26.85(a) or a hydration monitor is observing the donor during the hydration process, as permitted by the proposed change to § 26.109(b)(1). Second, § 26.89(d) would be revised to more precisely describe the actions taken by the collector when sealing the collection container with tamper-evident tape and completing the Federal CCF to end the collection process. The phrase “the urine specimen container has been sealed and initialed, the chain of custody form has been executed, and the donor has departed the collection site” would be replaced with the phrase “the urine specimen container has been sealed with tamper-evident tape, the seal has been dated and initialed, and the Federal CCF has been completed.” Third, the phrase “or when a refusal to test has been determined under § 26.107(d)” would be added to § 26.89(d) to more accurately describe when the collection process has been completed if a refusal to test has been determined. The three changes would improve the clarity of the existing collection requirements, correct an editorial error in the name of the form that is used to document the specimen collection, and include a reference to a refusal to test as another circumstance when the collection process is complete.

The proposed rule would revise § 26.107, “Collecting a urine specimen,” in four ways related to how the donor is observed. First, the proposed rule would redesignate paragraph (b) as paragraph (b)(1) of this section. Second, the phrase “, except as provided in § 26.109(b)(1),” would be added in the first sentence after “The collector shall pay careful attention to the donor during the entire collection process.”

This revision is necessary because of the proposed rule change to permit an individual other than the original specimen collector to monitor a donor in the hydration process; as a result, the original collector may not be present with the donor during the entire collection process. Third, § 26.107(b)(1) would be revised to replace the phrase “to note any conduct that clearly indicates an attempt to tamper with a specimen (e.g., substitute urine is in plain view or an attempt to bring an adulterant or urine substitute into the private area used for urination)” with the phrase “to observe any conduct that indicates an attempt to subvert the testing process (e.g., tampering with a specimen; having a substitute urine in plain view; attempting to bring an adulterant, urine substitute, temperature measurement device, and/or heating element into the room, stall, or private area used for urination).” The proposed changes would provide additional examples of subversion attempt actions that have been reported by licensees and other entities in the annual information reports required by § 26.719, “Reporting requirements.” More accurate examples of subversion attempts in the regulatory text provide additional clarity on donor actions that may be considered a subversion attempt. Lastly, the phrase “the collector shall document the conduct” in proposed § 26.107(b)(1) would be revised to “the collector shall document a description of the conduct,” which would improve the clarity of the existing regulatory requirement.

Section 26.107(b)(2) would be added to ensure that if a hydration monitor is used to observe a donor during the § 26.109(b) hydration process, this individual would immediately inform the collector of any donor conduct that may indicate an attempt to subvert the testing process, such as the donor leaving the collection site or refusing to follow directions. This rule change would be necessary because the collector must be informed of any unacceptable donor behavior so that appropriate action may be taken.

The proposed rule would revise § 26.89(c) to correct an editorial error in the instructions that a collector must provide to the donor regarding refusing to cooperate with the testing process. Currently, the word “adulterated” is used twice in the phrase “adulterated, diluted, or adulterated the specimen,” which describes the situation where a donor admits to subverting the testing process. The phrase would be revised to “adulterated, diluted, or substituted the specimen.”

The proposed rule would revise § 26.117, “Preparing urine specimens

for storage and shipping,” in three ways. First, the proposed rule would revise § 26.117(a) to add the phrase “Once the collector is presented with the specimen from the donor” at the beginning of the first sentence to clarify when the collector would begin to keep the donor’s “urine specimen(s) in view at all times.” This revision would improve the clarity of an existing activity in the collection process. For example, the collector would not be able to keep the donor’s urine specimen in view at all times when the donor is in the room, stall, or private area used for urination, as described in § 26.107(a). Second, two editorial errors would also be corrected in § 26.117(f): The term “chain-of-custody forms” would be replaced with the term “Federal CCFs” and the phrase “or the licensee’s testing facility” would be replaced with the phrase “or to the licensee testing facility.” Third, the proposed rule would revise § 26.117(g) to add the phrase “except as provided in § 26.109(b)(1)(ii), for the Federal CCF,” to describe an instance when the custody documents would not be under the control of the collector. This change is needed because the proposed rule change to § 26.109(b)(1)(ii) would permit another collector or hydration monitor to observe the donor during the hydration process and to maintain the Federal CCF during that time period.

With regard to urine specimen acceptability, the proposed rule would revise the term “altered,” as used in § 26.111(a) and (c), to clarify that the term means that the collector has determined that a specimen may have been adulterated and/or diluted. This determination by a collector is not equivalent to the determination that a specimen is an *adulterated specimen* as defined in § 26.5, which is a specimen testing determination made by an HHS-certified laboratory.

The proposed rule would correct an editorial error in § 26.111(a) associated with the minimum volume requirement for a urine specimen. Specifically, the phrase “but greater than 15 mL” would be replaced with “but equal to or greater than 15 mL.” This change conforms with the existing minimum specimen volume requirements in §§ 26.109(b)(4) and 26.111(b) and (d).

Collector Actions Following a Refusal To Test

The proposed rule would add § 26.107(d) and revise §§ 26.111(c) and (e) and 26.115(g) to more explicitly describe the actions that a collector must take when a refusal to test is determined during the specimen collection process, including the

retention or disposal of any specimen(s) provided by the donor.

Section 26.107(d) would be added to state that if the collector determines a refusal to test during the specimen collection process, the collector shall do the following: (1) Inform the donor that a refusal to test has been determined; (2) terminate the collection process; (3) document a description of the refusal to test on the Federal CCF; (4) discard any urine specimen(s) provided by the donor, unless provided for a post-event test in § 26.31(c)(3); and (5) immediately inform the FFD program manager of the refusal to test. The majority of these proposed changes are consistent with existing collector practice. However, the proposed change to discard any urine specimens, except if collected for a post-event test, would be a new requirement to improve the uniformity of licensee and other entity actions taken once a refusal to test had been determined. The NRC is aware of instances in which a licensee or other entity would conduct specimen testing, even though a refusal to test had already been determined at the collection site. This change would address this inconsistency. The proposed revisions to § 26.107(d) would help ensure that if a donor refuses to cooperate with the collection process, uniform action is taken, which would make 10 CFR part 26 consistent with Section 8.12 of the 2008 HHS Guidelines and improve its effectiveness.

The proposed change to retain and test any specimen collected for a post-event test in § 26.31(c)(3) would help to inform licensee root cause determinations, as required by other parts of the NRC’s regulations, such as §§ 20.2203(b), 50.73(b), and 70.50(c). Although a refusal to test determination at the collection site subsequent to a specimen being provided for a post-event test is a very rare occurrence, a regulatory framework is needed to enable the testing of an individual’s urine (or other specimen matrix such as oral fluid) to assist in determining whether the individual who committed or contributed to the event may have been impaired from the use of alcohol, an illegal drug, or prescription or over-the-counter medication. This assessment (which is informed by the requirements in §§ 26.185, “Determining a fitness-for-duty policy violation” and 26.189, “Determination of fitness”) is very important because post-event testing is conducted, in part, in response to the occurrence of a very significant event such as, but not limited to: (1) A death, (2) a significant illness or personal injury, (3) a radiation exposure or release of radioactivity in

excess of regulatory limits, or (4) an actual or potential substantial degradation of the level of safety of the plant.

Section 26.111(c) would be revised to remove the word “designated” from the phrase “designated FFD program manager.” This proposed change conforms with the existing terminology used in §§ 26.105(b), 26.109(b)(3), 26.111(c), 26.115(a), (b), and (h), and 26.139(b).

Section 26.111(e) specifies that “as much of the suspect specimen as possible must be preserved.” The proposed rule would add the clarifying phrase “except under the conditions described in § 26.107(d)(4)” to reference the conditions when a collector is to discard any urine specimen(s) collected. This change aligns with the proposed changes to § 26.107(d).

Some participants at the public meeting on October 11, 2011, requested that the NRC consider eliminating § 26.111(f) because they believe this particular requirement is unnecessary. Section 26.111(f) defines the criteria for an acceptable urine specimen as free from apparent contaminants, of at least 30 mL in quantity, and within the acceptable temperature range. However, this requirement does not aid in the implementation of 10 CFR part 26 and is not used in the NRC’s drug testing requirements. The participants stated that this provision is unnecessary because other sections in 10 CFR part 26 require specimens that do not meet the criteria in § 26.111(f) to be sent to an HHS-certified laboratory for testing. The NRC agrees that this requirement is unnecessary because other sections in the rule already provide explicit detail as to the determination of whether a specimen is valid or invalid, as well as the specific steps required if either determination is made. Section 26.109, “Urine specimen quantity,” contains provisions regarding urine specimen quantity; § 26.111(a) contains provisions regarding specimen temperature; and § 26.111(d) requires that any specimen a collector suspects has been adulterated, diluted, substituted, or that is collected under direct observation must be sent to an HHS-certified laboratory for initial and, if necessary, confirmatory testing. Therefore, the NRC is proposing to remove § 26.111(f) to improve the clarity of 10 CFR part 26.

Section 26.115(g) states that a donor declining to allow a directly observed collection is an act to subvert the testing process. The proposed rule would include a new requirement that in this instance “the collector shall follow the procedures in § 26.107(d).” This proposed requirement describes the

actions that the collector must take when a refusal to test has been determined during the specimen collection process.

The NRC also received a public comment regarding the retention or disposal of a urine specimen. The commenter recommended that the initially collected specimen be retained, unless the MRO or FFD program manager determined that a directly observed collection was necessary and the donor refused to comply, which the NRC interpreted as a reference to § 26.111(c) of the regulations. Section 26.111(c) requires the collector to contact the FFD program manager if there is reason to believe that a donor may have attempted to adulterate, dilute, or substitute a specimen based on the physical characteristics of a specimen (e.g., temperature, color, odor, presence of a precipitant) or other observations made during the collection. The FFD program manager may consult with the MRO to determine if the donor has attempted to subvert the testing process, and the FFD program manager or the MRO may require the donor to provide a second specimen, as soon as possible, and under direct observation. This section also requires the collector to inform the donor that he or she may volunteer to submit a second specimen under direct observation. The NRC has determined that there is no regulatory necessity to maintain any specimen provided by a donor, who has subsequently refused to cooperate or otherwise subverted the testing process, unless this specimen was for a post-event test, as required by § 26.31(c)(3). This approach is justified because upon such a determination, the donor who refuses to test is permanently denied authorization to have the types of access or perform the activities described in paragraphs (a) through (d) of § 26.4, “FFD program applicability to categories of individuals,” regardless of the outcome of the drug test. Therefore, the NRC is not proposing a rule change based on the public comment.

Blind Performance Test Sample Lot In-Service Requirement

The proposed rule would revise § 26.168(h)(1), which currently requires blind performance test sample (BPTS) suppliers to place a sample lot in service for no more than 6 months. Feedback received from industry and BPTS suppliers indicates that sample lots can remain viable for much longer than 6 months (e.g., 2 years). Further, Section 10.2 of the 2008 HHS Guidelines does not impose an in-service limit on BPTS lots. The NRC is proposing to eliminate the 6 month use

limit and to enable the BPTS supplier, based on laboratory testing data on lot stability, to establish a specified shelf-life for each BPTS sample lot. Allowing the BPTS supplier to determine the expiration date, instead of the NRC requiring a uniform shelf life, would improve the effectiveness of 10 CFR part 26, reduce burden on BPTS suppliers and entities implementing 10 CFR part 26 requirements, and align with the 2008 HHS Guidelines. Furthermore, if a BPTS is no longer stable and unexpected test results were reported by the laboratory inconsistent with the formulation, § 26.719(c) already requires the licensee or other entity to report to the NRC the testing error and the results of the investigation. The § 26.719(c) reporting requirement ensures that the NRC receives timely information on any BPTS formulation irregularities.

HHS-Certified Laboratory Personnel Qualifications and Responsibilities

The proposed rule would remove § 26.155, “Laboratory personnel,” which re-states the qualifications and responsibilities of HHS-certified laboratory personnel (e.g., Responsible Person, Certifying Scientist) included in the HHS Guidelines. The NRC finds that it is unnecessary to restate these HHS Guidelines requirements in 10 CFR part 26 because licensees and other entities are required to use HHS-certified laboratories to conduct drug and validity testing in § 26.153(a). Each laboratory is certified and then inspected every 6 months by the NLCP, which provides assurance that laboratory personnel are appropriately trained, qualified, and meet acceptable academic and technical requirements. The proposed change would reduce the potential for dual regulation of HHS-certified laboratories because each laboratory is also annually inspected by the licensee or other entity as required in § 26.41(c). Eliminating these redundant requirements would improve the regulatory efficiency of 10 CFR part 26 by reducing unnecessary regulatory oversight.

A conforming change based on the removal of § 26.155 would be to eliminate the reference to § 26.155 in § 26.8, “Information collection requirements; OMB approval,” which lists the information collection requirements in 10 CFR part 26 that were approved by the Office of Management and Budget (OMB).

HHS-Certified Laboratory Procedures

The proposed rule would remove § 26.157(b) through (e), which re-state the laboratory procedures requirements included in the HHS Guidelines.

Section 26.157, “Procedures,” describes the written procedures that HHS-certified laboratories must develop, implement, and maintain. The NRC finds that it is unnecessary to restate these HHS Guidelines requirements in 10 CFR part 26 because licensees and other entities are required to use HHS-certified laboratories to conduct drug and validity testing in § 26.153(a). As discussed for the proposed changes to § 26.155, each HHS-certified laboratory is certified and then inspected on a periodic basis by the NLCP, which provides assurance that the procedures requirements in the HHS Guidelines are developed, implemented, and maintained by the laboratory. The proposed change would reduce the potential for dual regulation of HHS-certified laboratories with respect to maintaining a duplicative set of laboratory procedures already required to be maintained by the HHS Guidelines and reviewed and evaluated by the NLCP.

The proposed rule would revise § 26.157(a) to replace the phrase “develop, implement, and maintain clear and well-documented procedures for accession, receipt, shipment, and testing of urine specimens” with “develop, implement, and maintain procedures specific to this part that document the accession, receipt, shipment, and testing of specimens.” The proposed changes would do the following: (1) Ensure that each laboratory would continue to maintain procedures specific to 10 CFR part 26, such as for special analyses testing in § 26.163(a) and the use of more stringent testing cutoff levels and/or the testing of additional substances permitted in § 26.31(d)(3); (2) remove the word “urine” from the phrase “testing of urine specimens” to provide additional flexibility, should the testing of additional specimen matrices (e.g., hair, oral fluids) be allowed by future changes to the HHS Guidelines and subsequent amendments to 10 CFR part 26 requirements; and (3) replace “clear and well-documented” with “documented” laboratory procedures to better align with the terminology in § 26.27(c) and the 2008 HHS Guidelines. The proposed changes to § 26.157(a) would enhance regulatory efficiency and reduce burden by clarifying that each laboratory must maintain procedures specific only to 10 CFR part 26 testing.

Quality Control Samples for Validity and Drug Testing

Section 26.137(e)(6) lists the specifications for the quality control samples to be included in each

analytical run of initial drug testing performed at an LTF, and § 26.167(d)(3) and (e) list the quality control sample specifications to be included in each analytical run of initial and confirmatory drug tests performed at an HHS-certified laboratory, respectively. The proposed rule would make a number of conforming changes to these quality control sample requirements to improve the clarity of 10 CFR part 26 and its consistency with Sections 11.12, 11.14, and 11.15(a)(1) of the 2008 HHS Guidelines.

The proposed rule would replace the word “drugs” in the first sentence of § 26.137(e)(6) and the phrase “drug and metabolite” in the second sentence of § 26.137(e)(6) with “drugs and drug metabolites” and “drug and drug metabolite,” respectively. The phrases “drug(s) or drug metabolite(s)” in § 26.137(e)(6)(ii) and (e)(6)(iii) and “a drug(s) or drug metabolite(s)” in § 26.167(d)(3)(ii), (d)(3)(iii), and (e)(3)(iii) would be replaced with the phrase “the drug or drug metabolite.” Similarly, the phrase “no drug” would be expanded to “no drug or drug metabolite” in § 26.167(e)(3)(i), and the phrase “no drugs or drug metabolites” would be revised to “no drug or drug metabolite” in §§ 26.137(e)(6)(i) and 26.167(d)(3)(i).

The proposed rule would remove the parenthetical phrase “(i.e., negative urine samples)” from §§ 26.137(e)(6)(i) and 26.167(d)(3)(i) and (e)(3)(i). Each of those requirements already specifies that the quality control sample is to contain no drug or drug metabolite, so the parenthetical is redundant.

The phrase “targeted at 25 percent below the cutoff” would be replaced in the proposed rule with the phrase “targeted at 75 percent of the cutoff” in §§ 26.137(e)(6)(iii) and 26.167(d)(3)(iii).

The term “sample(s)” would be replaced in the proposed rule with the phrase “at least one control” in §§ 26.137(e)(6)(i) and 26.167(d)(3)(i) and (e)(3)(i). Similarly, the phrase “at least one calibrator or control that is” would be replaced in the proposed rule with the phrase “at least one control” in § 26.167(e)(3)(iv).

The parenthetical statement “(i.e., calibrators and controls)” would be added after the phrase “quality control samples” in §§ 26.137(e)(6) and 26.167(d)(4), and a conforming change would be made in § 26.167(e)(2) to the phrase “calibrators and controls” by replacing it with the phrase “quality control samples (i.e., calibrators and controls).”

The phrase “Positive calibrator(s) and control(s) with a drug(s) or drug metabolite(s)” in § 26.167(e)(3)(ii)

would be replaced in the proposed rule with the phrase “A calibrator with its drug concentration at the cutoff.”

The proposed rule would replace the phrase “A minimum of 10 percent of all specimens in each analytical run” in § 26.137(e)(6) with the phrase “A minimum of 10 percent of the total specimens in each analytical run,” to more clearly describe how to determine the number of quality control samples to include in each analytical run of initial drug testing performed at an LTF. Conforming changes would be made in § 26.167(e)(2) to the quality control samples that are to be included in each analytical run of confirmatory drug tests performed at an HHS-certified laboratory, by replacing the phrase “At least 10 percent of the samples in each analytical run of specimens” with the phrase “A minimum of 10 percent of the total specimens in each analytical run.” The proposed change to § 26.167(e)(2) is consistent with the existing terminology used in the quality control sample requirement for initial drug testing in § 26.167(d)(4).

Section 26.167(f)(3) would be revised to make an editorial correction to the phrase “a statement by the laboratory’s responsible person” by capitalizing the “r” and the “p” in the position title, so that it reads as follows: “Responsible Person.”

The proposed rule would also correct two of three inaccuracies described in an NRC enforcement guidance memorandum (EGM–09–003, dated March 31, 2009) that pertain to the LTF quality control sample requirements for initial validity testing in § 26.137(d)(5) and for initial drug testing in § 26.137(e)(6)(v). The third inaccuracy, incorrectly using the term “laboratory analysts” instead of “licensee testing facility technicians,” has already been addressed in a 10 CFR part 26 final rule correcting amendment, which was published in the **Federal Register** on August 3, 2009 (74 FR 38326).

The first inaccuracy pertains to the requirements in § 26.137(d)(5) and (e)(6)(v), which require that at least one quality control specimen in each analytical run must appear as a “donor specimen” instead of as a “normal specimen” to the LTF technician. To meet this requirement, a different individual would be required to prepare the quality control sample to ensure that the LTF technician that is conducting the specimen testing would be unaware of the origin of the sample. The current rule does not require that different individuals prepare quality control samples and conduct specimen testing. Without EGM–09–003, § 26.137(d)(5) and (e)(6)(v) would place an

unnecessary burden on licensees and other entities because additional LTF procedural changes would be necessary, including the use of an additional qualified person, either to prepare quality control samples or to conduct specimen testing. The majority of LTFs use a single LTF technician to prepare quality control samples and to perform specimen testing, which is consistent with the intent of the current rule. To correct this inaccuracy and to address the currently applicable enforcement discretion, the proposed rule would replace the phrase “donor specimen” with the phrase “normal specimen” in § 26.137(d)(5) and (e)(6)(v).

The second inaccuracy pertains to the requirement in § 26.137(e)(6)(v) that “at least one positive control” is to be included in each analytical run of initial drug testing of specimens at an LTF. The intent of this requirement is to verify the custody and control procedures and confirm the accuracy of initial drug testing performed at an LTF, neither of which require the use of only a positive quality control sample. Since § 26.137(e)(6)(ii) and (e)(6)(iii) already specify the positive quality control samples to be included in each analytical run, the proposed rule would replace the phrase “at least one positive control, certified to be positive by an HHS-certified laboratory” with the phrase “at least one quality control sample” in § 26.137(e)(6)(v).

The NRC would rescind EGM–09–003 if the proposed rule changes correcting these inaccuracies are finalized.

Additional MRO Review for Invalid Specimens With pH of 9.0 to 9.5

Section 26.185(f) describes the process that an MRO is to use to review invalid specimen test results. The proposed rule would redesignate paragraph (f)(3) as paragraph (f)(4) and would add a new paragraph (f)(3) to § 26.185, to align the MRO review process for invalid specimen test results with Section 13.4(f) of the 2008 HHS Guidelines. Specifically, if a donor did not provide an acceptable medical explanation to the MRO for a pH value in the range of 9.0 to 9.5, the MRO would then have to consider if elapsed time and/or high temperature might have caused the test result. This change is being proposed because of research that demonstrated that exposing a urine specimen to high temperature and/or an extended delay in specimen testing from the time of collection may result in a pH in the range of 9.0 to 9.5 (Cook, et al., 2007). The 2008 HHS Guidelines addressed this topic in Section 13.4(f). In the proposed rule, if the MRO obtains sufficient information from the licensee

or other entity, collection site, LTF, or HHS-certified laboratory regarding elapsed time and/or temperature conditions at specimen collection, receipt, transportation, or storage to conclude that an acceptable technical explanation exists for the invalid test result due to pH, then the MRO would direct the licensee or other entity to collect a second urine specimen from the donor, as soon as reasonably practicable. The second specimen would not be collected under direct observation because sufficient evidence was obtained to conclude that donor action likely was not the cause of the invalid test result. This proposed new step to consider technical explanations for a discrepant pH result would provide an additional protection to the donor and limit the instances in which a second collection under direct observation is necessary (*i.e.*, only for invalid specimen test results where no legitimate medical or technical explanation has been determined by the MRO). While Section 13.4(f) of the 2008 HHS Guidelines differs in that it does not require a second test in these circumstances, this approach is inapplicable because a valid test is necessary for determining whether to grant or deny authorization.

Based on feedback received during the October 11, 2011, public meeting, the NRC has chosen not to propose adding detailed instructions in 10 CFR part 26 on how the MRO is to interpret time and temperature information with respect to specimen pH. Meeting participants commented that the draft instructions presented by the NRC at the public meeting were too prescriptive and unnecessary and that the MRO should be provided with flexibility in making this determination. The NRC agreed and instead is proposing to include guidance on the methods an MRO could use to review invalid test results reported in § 26.185(f)(3) in draft regulatory guide (DG) 5040, "Urine Specimen Collection and Test Result Review under 10 CFR part 26, Fitness for Duty Programs." This draft guidance is being issued concurrently for comment with this proposed rule.

The NRC also discussed at the October 11, 2011, public meeting the potential to change § 26.131(b)(2) to assist in the documentation of time and/or temperature information for invalid test results, based on a pH of 9.0 or greater obtained at an LTF. However, participants opposed these documentation requirements because they would be burdensome to implement. The NRC agreed and instead is proposing to include in DG-5040 the methods that LTF staff may use to

document information to support the MRO review of invalid test results in § 26.185(f)(3).

Donor Request for Specimen Retesting or Bottle B Testing

Section 26.165(b)(2) instructs the MRO to "inform the donor that he or she may, within 3 business days of notification by the MRO of the confirmed positive, adulterated, or substituted test result, request the retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen."⁷ The proposed rule would include a new requirement in § 26.165(b)(2) for the MRO to document in his or her records the date and time a request was received from the donor to retest an aliquot of the single specimen or to test the Bottle B split specimen. Documenting when a donor initiated the request for testing would ensure that a record was maintained to demonstrate that the donor had made the request within the required 3 business days timeframe. This rule change would document an existing practice of MROs when receiving such a request.

Section 26.165(b)(3) requires the donor to provide his or her permission for the retesting of an aliquot of the single specimen or the testing of Bottle B and states that "Neither the licensee, MRO, NRC, nor any other entity may order retesting of the single specimen or testing of the specimen in Bottle B without the donor's written permission, except as permitted in § 26.185(l)." The proposed rule would revise § 26.165(b)(3) to state that "No entity, other than the MRO as permitted in § 26.185(l), may order the retesting of an aliquot of a single specimen or the testing of the Bottle B split specimen." The proposed change would address an inconsistency in the current rule because § 26.165(b)(2) already states that the "donor's request may be oral or in writing." At present, even though the MRO may have received an oral request from the donor to proceed with the retesting of an aliquot of a single specimen or to test the Bottle B split specimen, some licensees are interpreting the current rule to require that the MRO must receive written permission from the donor before initiating the retesting of a specimen.

⁷ "Aliquot" means a portion of a specimen that is used for testing. It is taken as a sample representing the whole specimen. "Bottle B testing" means the drug or validity testing performed by a second HHS-certified laboratory on the split (Bottle B) specimen to verify the test results reported by the first HHS-certified laboratory that tested the Bottle A specimen.

These proposed changes to § 26.165(b)(2) and (b)(3) would improve the consistency of 10 CFR part 26 with Section 14.1(b) of the 2008 HHS Guidelines and would enhance due process by ensuring that the retesting of an aliquot of a single specimen or the testing of the Bottle B split specimen could proceed as quickly as possible.

Collection of a Second Specimen Under Direct Observation When Bottle B or an Aliquot of a Single Specimen Is Not Available for Testing

Section 26.115(a) lists the exclusive grounds for collecting a urine specimen under direct observation. However, the list does not include an existing requirement in § 26.165(f)(2) in which an observed collection is required when a donor requests a retest and either Bottle B or the single specimen is not available, due to circumstances outside of the donor's control. The proposed rule would correct this omission by including a new paragraph (a)(5) to reference the direct observation requirement in § 26.165(f)(2).

Section 26.165(f)(2) requires MRO action for a positive drug test result or an adulterated or substituted validity test result when the Bottle B of a split specimen or an aliquot of a single specimen is not available for testing at the donor's request. In this instance, the MRO is required to cancel the initial test result and inform the licensee or other entity that a second specimen must be collected under direct observation "as soon as reasonably practical." Section 14.1(c) of the 2008 HHS Guidelines, for this same circumstance, states that no advanced notice is to be provided to the donor regarding the second specimen collection until immediately before the collection is to commence. The proposed rule would revise the requirement in § 26.165(f)(2) to specify that no prior notice shall be given to a donor until immediately before the collection. Clarifying the procedure to follow in this circumstance would improve the effectiveness of licensees' or other entities' testing programs to detect illegal drug use and/or the misuse of legal drugs and would align 10 CFR part 26 with the 2008 HHS Guidelines.

The proposed rule would also revise § 26.165(f)(2) to state that the MRO is to report a cancelled test result to the licensee or other entity. The process in § 26.165(f)(2) already states that the licensee or other entity may not impose any sanctions on the donor for a cancelled test result. This revision clarifies the existing action that the MRO must take to report the results of the testing of a donor's specimen to the licensee or other entity. Subsequent

action by the licensee or other entity cannot be taken until the MRO provides the test result information for a donor's specimen. The revision would also state that the licensee or other entity must continue the administrative withdrawal of an individual's FFD authorization until the test results from the second specimen collection are determined. Continuing to administratively withdraw an individual's authorization would be consistent with § 26.165(f)(1), which requires the licensee or other entity to administratively withdraw an individual's FFD authorization on the basis of the first confirmed positive, adulterated, or substituted test result until the results of a donor-requested Bottle B split specimen test or single specimen retest are available and have been reviewed by the MRO.

A participant at the October 11, 2011, public meeting also requested that the NRC include in § 26.165(f)(2) a reference to §§ 26.129(b)(2) and 26.159(b)(2) to clarify that the action of the licensee or other entity was taken based on the test results of the second specimen collected under direct observation. The NRC agrees with this request and is proposing to revise this section accordingly.

FFD Program Performance Data Reporting

The NRC has periodically received questions from licensees and other entities on the annual drug and alcohol testing reporting requirements on "populations tested" in § 26.717(b) and (c). Specifically, the reporting requirements to provide FFD program performance data by populations tested "(i.e., individuals in applicant status, permanent licensee employees, [contractors/vendors] C/Vs)" has resulted in two types of questions.

First, licensees already report the pre-access testing results separately for the licensee employee and C/V tested populations, so they requested clarification on the term "individuals in applicant status." Applicant status is not a distinct tested population category, rather, it is the status of individuals that are subject to pre-access testing. Currently, licensees and other entities must report the test results by tested population for each condition of testing (i.e., pre-access, random, for-cause, post-event, and follow-up) as required by § 26.717(b)(5). By reporting the pre-access test results for each of the two tested populations (i.e., licensee employees, C/Vs), licensees and other entities are already reporting the results for individuals in "applicant status." To improve the clarity of the existing reporting requirement, the proposed

rule would remove the phrase "individuals in applicant status" from § 26.717(b)(3) and (b)(4).

Second, the NRC has received questions from entities other than the licensees that report § 26.717 drug and alcohol test results. Because § 26.717(b)(3) and (b)(4) does not specify "other entity" in the parenthetical statements defining the tested populations, these entities were unclear on how to classify their tested populations on the § 26.717 annual summary reports to the NRC. To correct this oversight, the proposed rule would revise the tested population "licensee employees" to "licensee or other entity employees" in § 26.717(b)(3) and (b)(4).

IV. Section-by-Section Analysis

Nomenclature Changes

Throughout 10 CFR part 26, the NRC is proposing to revise the term "custody and control form" to read "Federal CCF." Two additional iterations of the term, "custody-and-control forms" and "custody-and-control form(s)," would also be revised to read "Federal CCFs" and "Federal CCF(s)," respectively.

Throughout 10 CFR part 26, the NRC is proposing to revise the term "chain-of-custody" to read "chain of custody."

The nomenclature changes to "custody-and-control form" and "chain-of-custody" would align with the spelling of these terms in the 2008 HHS Guidelines and would also improve consistency in 10 CFR part 26.

The proposed rule would also correct a number of instances where "chain-of-custody form" was used instead of "custody and control form," and vice versa. These corrections pertain to §§ 26.89(d); 26.117(f); and 26.159(c), (d) and (e), as described later in this section.

§ 26.4 FFD Program Applicability to Categories of Individuals

Section 26.4(e)(6)(iv) would be revised to eliminate the phrase "(65 FR 41944; August 9, 2001)."

Section 26.4(g)(6) would be added to describe a new activity that the FFD program personnel could perform: Monitoring a donor during the hydration process described in § 26.109(b). The punctuation at the end of § 26.4(g)(4) and (5) would be updated to accommodate the addition of § 26.4(g)(6).

Section 26.4(j)(3) would be revised to replace the phrase "laboratory certified by the Department of Health and Human Services (HHS)" with "Department of Health and Human Services (HHS)-certified laboratory as defined in § 26.5."

§ 26.5 Definitions

As described in Section III.C of this document, the NRC is proposing to add definitions for *Cancelled test*, *Carryover*, *Certifying Scientist*, *Federal custody and control form*, *Lot*, *Rejected for testing*, and *Responsible Person*.

The definition for *calibrator* would be revised to include a clarifying statement that a calibrator is a solution of known concentration "in the appropriate matrix." The phrase "test specimen/sample" would be replaced with the phrase "donor specimen or quality control sample." The last sentence of the current definition which states that "calibrators may be used to establish a cutoff concentration and/or a calibration curve over a range of interest" would be deleted.

The definition for *control* would be revised by replacing the phrase "a sample used to monitor the status of an analysis to maintain its performance within predefined limits" with the phrase "a sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits."

The definition for *dilute specimen* would be revised by replacing the phrase "concentrations that are lower than expected for human urine" with the phrase "values that are lower than expected but are still within the physiologically producible ranges of human urine."

The definition for *HHS-certified laboratory* would be revised to eliminate the **Federal Register** citations for each final version of the HHS Guidelines. Instead, the definition would state that "*HHS-certified laboratory* means a laboratory that is certified to meet the standards of the *Mandatory Guidelines for Federal Workplace Drug Testing Programs* (the HHS Guidelines) at the time that drug and validity testing of a specimen is performed for a licensee or other entity."

The definition for *invalid result* would be revised to replace the phrase "for a specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, contains inconsistent physiological constituents, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result" with the phrase "in accordance with the criteria established in § 26.161(f) when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test."

The definition for *limit of quantitation (LOQ)* would be revised to replace the phrase “the lowest concentration of an analyte at which the concentration of the analyte can be accurately determined under defined conditions” with the phrase “for quantitation assays, the lowest concentration at which the identity and concentration of the analyte can be accurately established.”

The definition for *substituted specimen* would be revised to replace the phrase “with creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human physiology” with the phrase “a specimen that has been submitted in place of the donor’s urine, as evidenced by creatinine and specific gravity values that are outside the physiologically producible ranges of human urine.”

§ 26.8 Information Collection Requirements: OMB Approval

Section 26.8(b) would be revised to remove the reference to § 26.155.

§ 26.31 Drug and Alcohol Testing

Section 26.31(b)(2) would be revised to eliminate the phrase “(65 FR 41944; August 9, 2001).”

Section 26.31(d)(1) would be revised to include MDMA and MDA as substances for which licensees and other entities are required to test in each specimen.

Section 26.31(d)(1)(i)(D) would be revised to eliminate the phrase “as specified in § 26.155(a).”

Section 26.31(d)(1)(ii) would be revised to replace the phrase “except if the specimen is dilute and the licensee or other entity has required the HHS-certified laboratory to evaluate the specimen in §§ 26.163(a)(2) or 26.168(g)(3) with the phrase “except if special analyses of the specimen is performed under § 26.163(a)(2) by the HHS-certified laboratory.”

§ 26.89 Preparing To Collect Specimens for Testing

Section 26.89(c) would be revised to replace the phrase “adulterated, diluted, or adulterated the specimen” with the phrase “adulterated, diluted, or substituted the specimen.”

Section 26.89(d) would be revised to include this phrase at the end of the first sentence: “, except as described in § 26.109(b)(1).” The second sentence in § 26.89(d) would be revised in three ways. First, the phrase “For this purpose, a urine collection” would be replaced with the phrase “The urine collection.” Second, the phrase “sealed and initialed” would be replaced with

the phrase “sealed with tamper-evident tape, the seal has been dated and initialed.” Finally, the phrase “the chain of custody form has been executed, and the donor has departed the collection site” would be replaced with the phrase “and the Federal CCF has been completed or when a refusal to test has been determined under § 26.107(d).”

§ 26.107 Collecting a Urine Specimen

Section 26.107(b) would be revised in four ways. First, the proposed rule would redesignate paragraph (b) as paragraph (b)(1) of this section. Secondly, the phrase “except as provided in § 26.109(b)(1)” would be added in the first sentence after “The collector shall pay careful attention to the donor during the entire collection process.” Third, § 26.107(b) would be revised to replace the phrase “to note any conduct that clearly indicates an attempt to tamper with a specimen (e.g., substitute urine is in plain view or an attempt to bring an adulterant or urine substitute into the privacy area)” with the phrase “to observe any conduct that indicates an attempt to subvert the testing process (e.g., tampering with a specimen; having a substitute urine in plain view; attempting to bring an adulterant, urine substitute, heating element, and/or temperature measurement device into the room, stall, or private area used for urination).” Lastly, the phrase “the collector shall document the conduct” would be revised to read as follows: “the collector shall document a description of the conduct.”

Section 26.107(b)(2) would be added to ensure that if a hydration monitor is used to observe a donor during the § 26.109(b) hydration process, this individual shall immediately inform the collector of any donor conduct that may indicate an attempt to subvert the testing process (e.g., donor leaves the collection site, donor refuses to follow directions).

Section 26.107(d) and (d)(1) through (d)(5) would be added to describe requirements regarding the actions a collector must take if a refusal to test is determined at any point during the specimen collection process. Specifically, the collector shall: (1) Inform the donor that a refusal to test has been determined, (2) terminate the collection process, (3) document a description of the refusal to test on the Federal CCF, (4) discard any urine specimen(s) provided by the donor unless the specimen was collected for a post-event test required by § 26.31(c)(3), and (5) immediately inform the FFD program manager of the refusal to test.

§ 26.109 Urine Specimen Quantity

Section 26.109(b)(1) would be revised, and new paragraphs (b)(1)(i) through (b)(1)(iii) would be added to provide a licensee or other entity with new flexibility in the personnel that may be used to monitor a donor during the hydration process that is initiated when a donor is unable to provide an acceptable quantity of urine during the initial collection attempt. For clarity, the last sentence of § 26.109(b)(1) would become the new first sentence of § 26.109(b)(2). The proposed rule would permit another staff member designated as FFD program personnel, as described in § 26.4(g)(6), or another specimen collector meeting the requirements in § 26.85(a), instead of the specimen collector who initiated the collection process, to monitor a donor during the hydration process. The collector shall (1) explain the hydration process and acceptable donor behavior to the hydration monitor and (2) record the name of the individual observing the donor on the Federal CCF and then provide the Federal CCF to the observer for the duration of the hydration process. The original collector may then perform other collections while the donor is in the hydration process.

§ 26.111 Checking the Acceptability of the Urine Specimen

Section 26.111(a) would be revised to replace the phrase “greater than 15 mL” with the phrase “equal to or greater than 15 mL” and to add the phrase “(e.g., adulterated or diluted)” after the word “altered.”

Section 26.111(c) would be revised to remove the word “designated” from the phrase “designated FFD program manager” in the first sentence. The parenthetical phrase “(e.g., adulterated or diluted)” would be added after the word “altered” in the second sentence.

Section 26.111(e) would be revised to include the phrase “, except under the conditions described in § 26.107(d)(4)” at the end of the existing requirement.

Section 26.111(f) would be removed.

§ 26.115 Collecting a Urine Specimen Under Direct Observation

Section 26.115(a)(3) would be revised to replace the phrase “The collector observes conduct clearly and unequivocally indicating an attempt to dilute, substitute, or adulterate the specimen” with the phrase “The collector, or the hydration monitor if one is used as permitted in § 26.109(b)(1), observes conduct by the donor indicating an attempt to subvert the testing process.” Also, the proposed rule would remove the word “and” at

the end of § 26.115(a)(3). Paragraph (a)(5) would be added to include an additional instance when an observed collection is required: “The donor requests a retest and either Bottle B or the single specimen is not available due to circumstances outside of the donor’s control, as specified in § 26.165(f)(2).” The period at the end of the sentence in § 26.115(a)(4) would be replaced with a “; or” to accommodate for the new paragraph (a)(5) of this section in the list of exclusive grounds for performing a directly observed collection.

In § 26.115(f), the proposed rule would revise the first sentence, “If someone other than the collector is to observe the collection, the collector shall instruct the observer to follow the procedures in this paragraph,” so that it reads “If the observer is not a trained collector, the collector shall, in the presence of the donor, instruct the observer on the collection procedures in paragraph (f) of this section.” The revised sentence would be added to the end of existing requirements in § 26.115(e).

In § 26.115(f)(2), the proposed rule would add the following statement to the end of the existing requirement: “A reflective mirror may be used to assist in observing the provision of the specimen only if the physical configuration of the room, stall, or private area is not sufficient to meet this direct observation requirement; the use of a video camera to assist in the observation process is not permitted.”

In § 26.115(f)(3), the proposed rule would replace the phrase “If the observer is not the collector, the observer may not take the collection container from the donor, but shall observe the specimen as the donor takes it to the collector” with the phrase “If the observer is not the collector, the observer may not touch or handle the collection container but shall maintain visual contact with the specimen until the donor hands the collection container to the collector.”

Section 26.115(g) would be revised to include the phrase “, and the collector shall follow the procedures in § 26.107(d)” at the end of the existing requirement.

§ 26.117 Preparing Urine Specimens for Storage and Shipment

Section 26.117(a) would be revised to add the phrase “Once the collector is presented with the specimen from the donor” at the beginning of the first sentence to clarify when the collector would begin to keep the donor’s “urine specimen(s) in view at all times.”

Section 26.117(f) would be revised to replace the term “chain-of-custody

forms” with the term “Federal CCFs.” Section 26.117(f) would also be revised to replace the phrase “or the licensee’s testing facility,” with the phrase “or to the licensee testing facility.”

Section 26.117(g) would be revised to add the phrase “, except as provided in § 26.109(b)(1)(ii) for the Federal CCF,” to the end of the first sentence.

§ 26.129 Assuring Specimen Security, Chain of Custody, and Preservation

Section 26.129(b)(1)(ii) would be revised by replacing the phrase “the specimen may not be tested,” with the phrase “the licensee testing facility shall reject the specimen for testing.”

Section 26.129(b)(2) would be revised by adding the phrase “and report a cancelled test result to the licensee or other entity,” after the phrase “requiring the MRO to cancel the testing of a donor’s urine specimen.”

§ 26.133 Cutoff Levels for Drugs and Drug Metabolites

The introductory paragraph under § 26.133 would be revised to clarify that the specified cutoff level must be used to determine whether the specimen is negative “or positive” for the indicated drug or drug metabolite being tested. The table in § 26.133 would be revised to: (1) Lower the initial test cutoff level for cocaine metabolites from 300 ng/mL to 150 ng/mL, (2) include a new footnote 1 to clarify that the initial test cutoff level for opiate metabolites is for codeine/morphine and that morphine is the target analyte, (3) lower the initial test cutoff level for amphetamines (abbreviated in the table as AMP) from 1000 ng/mL to 500 ng/mL, (4) add initial testing for 6-AM at a cutoff level of 10 ng/mL, (5) include a new table footnote 2 regarding initial test kits, (6) include a new table footnote 3 to clarify that for amphetamines testing, methamphetamine (abbreviated in the table as MAMP) is the target analyte, (7) add initial testing for MDMA and MDA at a cutoff level of 500 ng/mL, and (8) provide the full chemical name for MDMA and MDA in new footnotes 4 and 5 to the table, respectively. The column header “Drug or metabolites” in the table in § 26.133 would also be revised to “Drugs or drug metabolites” to align with the table title.

§ 26.137 Quality Assurance and Quality Control

Section 26.137(d)(5) would be revised to replace the term “donor specimen” with the term “normal specimen.”

Section 26.137(e)(6) would replace the phrase “A minimum of 10 percent of all specimens” at the start of the first sentence with the phrase “A minimum

of 10 percent of the total specimens.” The parenthetical phrase “(i.e., calibrators and controls)” would be added after the phrase “quality control samples” in the first sentence of § 26.137(e)(6). The word “drugs” in the first sentence of § 26.137(e)(6) and the phrase “drug and metabolite” in the second sentence of § 26.137(e)(6) would be replaced with the phrases “drugs and drug metabolites” and “drug and drug metabolite,” respectively.

Section 26.137(e)(6)(i) would replace the phrase “Sample(s) certified by an HHS-certified laboratory to contain no drugs or drug metabolites (i.e., negative urine samples)” with the phrase “At least one control certified by an HHS-certified laboratory to contain no drug or drug metabolite.”

Section 26.137(e)(6)(ii) would be revised to replace the phrase “drug(s) or drug metabolite(s)” with the phrase “the drug or drug metabolite.”

Section 26.137(e)(6)(iii) would be revised to replace the phrase “the drug(s) or drug metabolite(s) targeted at 25 percent below the cutoff” with the phrase “the drug or drug metabolite targeted at 75 percent of the cutoff.”

Section 26.137(e)(6)(v) would be revised to replace the phrase “At least one positive control, certified to be positive by an HHS-certified laboratory, which appears to be a donor specimen” with the phrase “At least one quality control sample that appears to be a normal specimen.”

§ 26.153 Using Certified Laboratories for Testing Urine Specimens

Section 26.153(a) would be revised to replace the phrase “laboratories certified under the Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs [published in the **Federal Register** on April 11, 1988 (53 FR 11970), and as amended, June 9, 1994 (59 FR 29908), November 13, 1998 (63 FR 63483), and April 13, 2004 (69 FR 19643)]” with the phrase “HHS-certified laboratories as defined in § 26.5.” The sentence “Information concerning the current certification status of laboratories is available from the Division of Workplace Programs, Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration, Room 815, 5600 Fishers Lane, Rockwall 2 Bldg., Rockville, Maryland 20857” would be removed.

Section 26.153(g) would be revised to replace the term “Federal custody-and-control form” with “Federal CCF” and the term “non-Federal form” with “non-Federal CCF.”

§ 26.155 Laboratory Personnel

Section 26.155 would be removed and reserved.

§ 26.157 Procedures

Section 26.157(a) would be revised to replace the phrase “clear and well-documented procedures for” with the phrase “procedures specific to this part that document the.” Section 26.157(a) would also be revised to remove “urine” in the phrase “testing of urine specimens.”

Section 26.157(b) would be removed and reserved, and § 26.157(c) through (e) would be removed.

§ 26.159 Assuring Specimen Security, Chain of Custody, and Preservation

Section 26.159(b)(1)(ii) would be revised to replace the phrase “the specimens may not be tested” with the phrase “the laboratory shall reject the specimens for testing” when the integrity or identity of the specimens is in question.

Section 26.159(b)(2) would be revised to add after “The following are exclusive grounds requiring the MRO to cancel the testing of a donor’s urine specimen,” the phrase “and report a cancelled test to the licensee or other entity.”

Section 26.159(c) would be revised in the second sentence of the paragraph to replace the term “custody-and-control” with the term “chain of custody.” Also, the term “custody-and-control form” would be replaced with the term “Federal CCF” in the third sentence of the paragraph.

Section 26.159(d) would be revised to replace the term “custody-and-control” with the term “chain of custody.”

Section 26.159(e) would be revised to replace the term “custody-and-control” with the term “chain of custody” in the two instances that it occurs in the paragraph.

§ 26.161 Cutoff Levels for Validity Testing

Sections 26.161(c)(3) through (c)(6) would be revised to replace all instances of “LOD” with “LOQ.”

Sections 26.161(c)(5) would be revised to replace the phrase “GC/MS for the confirmatory test” with the phrase “a different confirmatory method (e.g., gas chromatography/mass spectrometry (GC/MS)).”

Sections 26.161(c)(6) would be revised to replace the phrase “GC/MS for the confirmatory test” with the phrase “a different confirmatory method (e.g., GC/MS).”

Sections 26.161(f)(5) and (f)(7) would be revised to replace all instances of the term “LOD” with the term “LOQ.”

§ 26.163 Cutoff Levels for Drug and Drug Metabolites

Section 26.163(a)(1) would be revised to replace the phrase “negative for the indicated drugs and drug metabolites” with the phrase “negative or positive for the indicated drugs and drug metabolites.” The phrase “except if validity testing indicates that the specimen is dilute” would also be revised to “except as specified in paragraph (a)(2) of this section.”

The table in § 26.163(a)(1) would be revised to: (1) Lower the initial test cutoff level for cocaine metabolites from 300 ng/mL to 150 ng/mL, (2) include a new footnote 1 to clarify that the initial test cutoff level for opiate metabolites is for codeine/morphine and that morphine is the target analyte, (3) lower the initial test cutoff level for amphetamines (abbreviated in the table as AMP) from 1000 ng/mL to 500 ng/mL, (4) add initial testing for 6-AM at a cutoff level of 10 ng/mL, (5) include a new footnote 2 regarding initial test kits, (6) include a new footnote 3 to clarify that for amphetamines testing, methamphetamine (abbreviated in the table as MAMP) is the target analyte, (7) add initial testing for MDMA and MDA at a cutoff level of 500 ng/mL, and (8) provide the full chemical names for MDMA and MDA in new footnotes 4 and 5 to the table, respectively. The column header “Drug or metabolites” in the table in § 26.163(a)(1) would also be revised to “Drugs or drug metabolites” to align with the table title. Section 26.163(a)(2) would be revised to remove the phrase “At the licensee’s or other entity’s discretion, as documented in the FFD program policies and procedures, the licensee or other entity may require the” and replace the provision with “HHS-certified laboratories shall conduct special analyses of specimens as follows:”

Section 26.163(a)(2)(i) would be revised to replace the phrase “the HHS-certified laboratory shall compare the responses of the dilute specimen to the cutoff calibrator in each of the drug classes” with the phrase “or if a specimen is collected under direct observation for any of the conditions specified in § 26.115(a)(1) through (a)(3) or (a)(5).”

Section 26.163(a)(2)(ii) would be revised to state “If any immunoassay response is equal to or greater than 40 percent of the cutoff calibrator, the laboratory shall conduct confirmatory drug testing of the specimen to the LOQ for those drugs and/or drug metabolites; and.”

The table in § 26.163(b)(1) would be revised to: (1) Lower the confirmatory

test cutoff level for cocaine metabolite from 150 ng/mL to 100 ng/mL, (2) revise “Opiates” to read “Opiate metabolites,” (3) remove footnote 3 regarding the requirement that confirmatory testing of 6-AM only proceed when confirmatory testing shows a morphine concentration exceeding 2000 ng/mL, (4) lower the confirmatory test cutoff levels for amphetamine and methamphetamine from 500 ng/mL to 250 ng/mL, (5) redesignate footnote 4 as footnote 3 and revise the text to lower the concentration of amphetamine that must be present in the specimen from 200 ng/mL to 100 ng/mL, and (6) add confirmatory testing for MDMA and MDA at a cutoff level of 250 ng/mL. The column header “Drug or metabolites” in the table in § 26.163(b)(1) would also be revised to “Drugs or drug metabolites.”

§ 26.165 Testing Split Specimens and Retesting Single Specimens

A new fifth sentence would be added to § 26.165(b)(2) that states, “The MRO shall document in his or her records when (i.e., date and time) the request was received from the donor to retest an aliquot of the single specimen or to test the Bottle B split specimen.”

The first sentence in § 26.165(b)(3) would be deleted. The second sentence in § 26.165(b)(3) would be revised to state “No entity, other than the MRO as permitted in § 26.185(l), may order the retesting of an aliquot of a single specimen or the testing of the Bottle B split specimen.”

The last sentence in § 26.165(f)(1) would be revised by adding the phrase “the MRO shall report a cancelled test result to the licensee or other entity, and” to indicate that the MRO must report the cancelled test.

Section 26.165(f)(2) would be revised to clarify the actions that an MRO is to take when a donor requests testing of Bottle B or a retest of a single specimen and the specimen to be tested is unavailable due to circumstances outside of the donor’s control. Specifically, the proposed rule would: (1) Add instruction for the MRO to report a cancelled test to the licensee or other entity for the donor’s specimen; (2) add instruction for the licensee or other entity to perform a second collection without prior notice to the donor and to continue to administratively withdraw the individual’s authorization until the results of the second collection are received by the MRO; and (3) add a reference to §§ 26.129(b)(2) and 26.159(b)(2), which describes the circumstances that require the MRO to cancel a test result.

§ 26.167 Quality Assurance and Quality Control

Section 26.167(d)(3)(i) would be revised to replace the phrase “Sample(s) certified to contain no drugs or drug metabolites (*i.e.*, negative urine samples)” with the phrase “At least one control certified to contain no drug or drug metabolite.”

Section 26.167(d)(3)(ii) would be revised to replace the phrase “a drug(s) or drug metabolites” with the phrase “the drug or drug metabolite.”

Section 26.167(d)(3)(iii) would be revised to replace the phrase “a drug(s) or drug metabolite(s) targeted at 25 percent below the cutoff” with the phrase “the drug or drug metabolite targeted at 75 percent of the cutoff.”

Section 26.167(d)(4) would be revised to add the parenthetical statement “(*i.e.*, calibrators and controls)” after the phrase “quality control samples.”

Section 26.167(e)(2) would be revised to replace the phrase “At least 10 percent of the samples in each analytical run of specimens must be calibrators and controls” with the phrase “A minimum of 10 percent of the total specimens in each analytical run must be quality control samples (*i.e.*, calibrators and controls).”

Section 26.167(e)(3)(i) would be revised to replace the phrase “Sample(s) certified to contain no drug (*i.e.*, negative urine samples)” with the phrase “At least one control certified to contain no drug or drug metabolite.”

Section 26.167(e)(3)(ii) would be revised to replace the phrase “Positive calibrator(s) and control(s) with a drug(s) or drug metabolite(s)” with the phrase “A calibrator with its drug concentration at the cutoff.”

Section 26.167(e)(3)(iii) would be revised to replace the phrase “a drug(s) or drug metabolites” with the phrase “the drug or drug metabolite.”

Section 26.167(e)(3)(iv) would be revised to replace the phrase “At least one calibrator or control that is targeted” with the phrase “At least one control targeted.”

Section 26.167(f)(3) would be revised to make an editorial correction to the phrase “a statement by the laboratory’s responsible person” by capitalizing the position title in that phrase to “Responsible Person.”

§ 26.168 Blind Performance Testing

Section 26.168(h)(1) would be revised to remove the phrase “and for no more than 6 months” from this requirement.

§ 26.169 Reporting Results

Section 26.169(a) would be revised to correct the capitalization of the “c” and

the “s” in the position title in the phrase “the laboratory’s certifying scientist” to “Certifying Scientist.”

The HHS-certified laboratory annual statistical summary reporting requirements in § 26.169(h)(3) would be revised to add MDMA and MDA to the list of amphetamines test results that a laboratory must report as required by § 26.169(h)(3)(v). Additional conforming changes would be made to the names of the drugs and drug metabolites listed in § 26.169(h)(3) to include adding “(as THCA)” after “Marijuana metabolite” in § 26.169(h)(3)(i), adding “(as benzoylecgonine)” after “Cocaine metabolite” in § 26.169(h)(3)(ii), revising 6-AM to “6-acetylmorphine (6-AM)” in § 26.169(h)(3)(iii)(C), and revising “Phencyclidine” to “Phencyclidine (PCP)” in § 26.169(h)(3)(iv).

§ 26.183 Medical Review Officer

Section 26.183 would be revised to remove the phrase “at the licensee’s or other entity’s discretion” from § 26.183(c), (c)(1), and (d)(2)(ii).

§ 26.185 Determining a Fitness-for-Duty Policy Violation

Section 26.185(f)(3) would be redesignated as (f)(4), and a new paragraph (f)(3) would be added to state that if there is no legitimate technical or medical explanation for an invalid test result based on a pH result greater than or equal to 9.0 but less than or equal to 9.5, the MRO shall consider whether there is evidence of elapsed time, exposure of the specimen to high temperature, or both that could account for the pH value. If the MRO obtains objective and sufficient information regarding elapsed time, temperature conditions, or both to conclude that an acceptable explanation exists for the invalid test result due to pH, the MRO would direct the licensee or other entity to collect a second urine specimen from the donor as soon as reasonably practicable. This second specimen may not be collected from the donor under direct observation conditions.

Section 26.185(g)(2) would be revised to replace the phrase “If the licensee or other entity requires the HHS-certified laboratory to conduct the special analysis of dilute specimens permitted by § 26.163(a)(2), the results of the special analysis are positive,” with the phrase “If the results of the special analysis testing required by § 26.163(a)(2) are positive.”

Section 26.185(g)(2)(iii) would be revised to remove the phrase “clearly and unequivocally.”

Section 26.185(g)(3) would be removed.

Section 26.185(g)(4) and (g)(5) would be redesignated as § 26.185(g)(3) and (g)(4), respectively, and the cross-reference under § 26.163(a)(1) would be updated to reflect these changes.

§ 26.405 Drug and Alcohol Testing

Section 26.405(d) would be revised to add MDMA and MDA as substances for which licensees and other entities are required to test in each specimen.

§ 26.415 Audits

Section 26.415(c) would be revised to eliminate the phrase “(65 FR 41944; August 9, 2001).”

§ 26.717 Fitness-for-Duty Program Performance Data

Section 26.717(b)(3) would be revised to replace the phrase “(*i.e.*, individuals in applicant status, permanent licensee employees, C/Vs),” with the phrase “(*i.e.*, licensee and other entity employees, C/Vs).”

Section 26.717(b)(4) would be revised to replace the phrase “(*i.e.*, individuals in applicant status, permanent licensee employees, C/Vs),” with the phrase “(*i.e.*, licensee and other entity employees, C/Vs).”

V. Specific Requests for Comment

The NRC is seeking advice and recommendations from stakeholders on this proposed rule. We are particularly interested in comments and supporting rationale from the public on the following:

1. Alignment With the HHS Guidelines

Two proposed changes in this rule would eliminate redundant provisions in 10 CFR part 26 that also appear in the HHS Guidelines (*i.e.*, HHS-certified laboratory personnel qualifications requirements in § 26.155, “Laboratory personnel,” and HHS-certified laboratory procedures requirements specific to the HHS Guidelines in § 26.157, “Procedures”). Because the NLCP inspection process verifies laboratory compliance with the HHS Guidelines, additional review and oversight by NRC licensees and other entities (*e.g.*, of laboratory security requirements) would be duplicative. The NRC is seeking comment on additional provisions in 10 CFR part 26 that are consistent with the HHS Guidelines and could be eliminated from 10 CFR part 26.

2. Special Analyses Testing

The proposed rule includes new requirements in § 26.163(a)(2) for the special analyses testing of urine specimens for drugs and drug metabolites. The first would require

special analyses testing of specimens with dilute validity test results when initial drug testing identifies a drug or drug metabolite within 40 percent of the testing cutoff level. Currently, special analyses testing of dilute specimens is optional. The second new requirement would expand special analyses testing to specimens collected under direct observation as required by § 26.115(a)(1) through (a)(3) and new paragraph (a)(5). The NRC is seeking comment on whether special analyses testing should also apply to the testing of individuals that already have tested positive on a 10 CFR part 26 test (*i.e.*, denied unescorted access authorization by § 26.75(d) for a first or second drug testing positive result). Requiring special analyses testing in this case would add a level of assurance to follow-up testing required by § 26.69(b)(6), which is conducted to confirm continued abstinence from illegal drug use and/or the misuse of legal drugs.

3. Provide Flexibility To Conduct Additional Specimen Validity Tests

Section 26.31(d)(1)(i)(D) permits a licensee or other entity to utilize lower cutoff levels and drug testing assays without forensic toxicologist review if the HHS Guidelines are revised to authorize use of the assay and testing cutoff levels. However, § 26.161(h) prohibits licensees and other entities from using more stringent cutoff levels for validity tests. The NRC is seeking comment on whether § 26.161(h) should be revised to provide a licensee or other entity with the option to conduct additional specimen validity tests and/or to utilize lower cutoff levels if the HHS Guidelines are revised in the future to include such testing.

4. Effective Date of the Final Rule

If the proposed rule is finalized, the NRC anticipates providing a 60-day implementation period from the date that the final rule is published in the **Federal Register**. The effective date of the final rule and the compliance date for licensees and other entities would be 60 days after the date that the final rule is published in the **Federal Register**. The NRC is seeking comment on whether this implementation time period is appropriate based on the proposed rule changes.

5. Direct Observation of Specimen Collection

The proposed rule retains the requirement for direct observation during the collection of a second sample when there are indications of a subversion attempt during the initial collection. The NRC is seeking comment

on whether there are any effective alternatives to direct observation that will assist in preventing subversion of the drug testing process.

6. 2017 HHS Guidelines—New Test Analytes

On January 23, 2017, HHS issued its latest revision of the Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Urine Specimens (82 FR 7920). Subpart C, “Urine Drug and Specimen Validity Tests,” of the 2017 HHS Guidelines was revised to include additional initial and confirmatory test analytes for certain opioids; specifically, hydrocodone, hydromorphone, oxycodone, and oxymorphone. The NRC is seeking comment on whether §§ 26.31(d)(1) and 26.405(d) should be revised to identify hydrocodone, hydromorphone, oxycodone, and oxymorphone test substances, and whether §§ 26.133 and 26.163(a)(1) and (b)(1) should be revised to require initial and confirmatory testing of these drugs at the cutoff levels recommended in the 2017 HHS Guidelines.

7. Methylenedioxymethylamphetamine

The 2008 HHS Guidelines adds methylenedioxymethylamphetamine (MDEA) as a confirmatory analyte to the drug testing panel in Section 3.4. However, when the HHS revised the mandatory guidelines in 2017, HHS removed MDEA from Section 3.4 stating that “[t]he Department has evaluated the comments and has removed MDEA from the Guidelines (*i.e.*, MDEA is no longer included as an authorized drug in Section 3.4). The number of positive MDEA specimens reported by HHS-certified laboratories (*i.e.*, information provided to the Department through the NLCP) does not support testing all specimens for MDEA in federal workplace drug testing programs.” (82 FR 7920, 7923; January 23, 2017). The NRC is not proposing to adopt the 2008 HHS Guidelines’ addition of MDEA as a confirmatory test analyte at this time. As a result, the NRC is also proposing to add MDA to the initial testing panel to fully align with the “Ecstasy drugs” testing panel in the 2017 guidelines. The NRC is seeking comment on these changes.

VI. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the NRC certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This proposed rule affects the licensing and operation of nuclear power plants and Category I fuel cycle facilities. The

companies that own these facilities do not fall within the scope of the definition of “small entities” set forth in the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810).

The NRC estimates that none of the 67 entities affected by the rule would fall within the scope of the definition of “small entities” set forth in the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810). Therefore, the rule would not impact a substantial number of small entities.

VII. Regulatory Analysis

The NRC has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The NRC requests public comment on the draft regulatory analysis. The regulatory analysis is available as indicated in the “Availability of Documents” section of this document. Comments on the draft analysis may be submitted to the NRC as indicated under the **ADDRESSES** caption of this document.

VIII. Backfitting and Issue Finality

The proposed rule would apply to all current nuclear power plant licensees (including holders of renewed licenses under 10 CFR part 54, “Requirements for Renewal of Operating Licenses for Nuclear Power Plants,” and combined licenses under 10 CFR part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants”) and holders of licenses authorizing the possession, use, or transport of formula quantities of SSNM under 10 CFR part 70, “Domestic Licensing of Special Nuclear Material.” The proposed rule would apply to holders of a certificate of compliance or an approved compliance plan under the provisions of 10 CFR part 76, “Certification of Gaseous Diffusion Plants,” if the holder engages in activities involving formula quantities of SSNM. Some or all of the proposed rule would apply to: (i) Current and future applicants for combined licenses under 10 CFR part 52 who have been issued a limited work authorization (LWA) under § 50.10(e), if the LWA authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related structures, systems, and components (SSCs) under the LWA; (ii) combined license holders before the Commission has made the finding under § 52.103(g); (iii) power reactor construction permit applicants (under 10 CFR part 50, “Domestic Licensing of Production and Utilization Facilities”) who have been

issued an LWA, if the LWA authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA; (iv) power reactor construction permit holders; and (v) early site permit holders who have been issued an LWA, if the LWA authorizes the early site permit holder to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA.

The rule would constitute backfitting as defined under § 50.109(a)(1) for current holders of 10 CFR part 50 operating licenses and construction permits for power reactors and under § 70.76(a)(1) for applicable current 10 CFR part 70 licensees. The NRC has performed a backfit analysis consistent with NUREG/BR-0058, Revision 4, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission.” The backfit analysis can be found at appendix E of the regulatory analysis. The NRC has determined the backfitting is justified because: (1) There would be a substantial increase in the overall level of protection of the public health and safety or the common defense and security to be derived from the backfitting and (2) the costs of implementation and the annual costs would be justified in view of this increase.

Imposing the requirements of the proposed rule on current holders of combined licenses would represent an inconsistency with the issue finality provision applicable to combined licenses under § 52.98, “Finality of combined licenses; information requests.” Therefore, the NRC has addressed the criteria in § 52.98 that would allow imposition of the proposed rule on current holders of combined licenses, despite the issue finality accorded to the combined license holders. The NRC believes that the proposed rule may be imposed as a cost-justified substantial increase in the protection of the public health and safety or common defense and security. The bases for this determination are presented in the backfit analysis found in appendix F of the regulatory analysis.

Imposing the requirements of the proposed rule on current and future applicants for power reactor construction permits under 10 CFR part 50, part 70 licenses, or early site permits or combined licenses under 10 CFR part 52 would not constitute backfitting. Neither § 50.109, “Backfitting,” nor the issue finality provisions for early site permits or combined licenses under 10 CFR part 52 protect either a current or prospective applicant for a construction permit, part 70 license, early site permit,

or combined license from changes in the NRC rules and regulations. The NRC has long adopted the position that § 50.109 does not protect current or prospective applicants from changes in NRC requirements or guidance because the policies underlying § 50.109 are largely inapplicable in the context of a current or future application. This position also applies to each of the issue finality provisions under 10 CFR part 52.

The provisions under 10 CFR part 26 also apply to applicants for construction permits, early site permits, or combined licenses who have been issued an LWA, if the LWA authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA. As of September 16, 2019, no LWAs have been issued to an applicant for a construction permit, early site permit, or combined license, so no such entity is protected by the backfitting and issue finality provisions from the changes proposed in this rulemaking.

Similarly, no entity holds a certificate of compliance or an approved compliance plan under the provisions of 10 CFR part 76, so no entity is protected by the backfitting provisions of § 76.76, “Backfitting,” from the changes proposed in this rulemaking.

Draft Regulatory Guidance

The guidance in DG-5040 presents methods acceptable to the NRC for implementing portions of this proposed rule. The draft guide would apply to current holders of nuclear power plant licenses (including holders of renewed licenses under 10 CFR part 54 and combined licenses under 10 CFR part 52) and current holders of licenses authorizing the possession, use, or transport of formula quantities of SSNM under 10 CFR part 70. The DG would also apply to holders of a certificate of compliance or an approved compliance plan under the provisions of 10 CFR part 76 if the holder engages in activities involving formula quantities of SSNM.

The DG would also apply to the following current and future entities: (1) Applicants for combined licenses under 10 CFR part 52 who have been issued an LWA under § 50.10(e), if the LWA authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA; (2) combined license holders before the Commission has made the finding under § 52.103(g); (3) power reactor construction permit applicants (under 10 CFR part 50) who have been issued an LWA, if the LWA authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related

SSCs under the LWA; (4) power reactor construction permit holders; and (5) early site permit holders who have been issued an LWA, if the LWA authorizes the early site permit holder to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA, if these entities elect to implement an FFD program that meets the requirements of subparts A through H, N, and O of 10 CFR part 26.

Issuance of the DG in final form would not constitute backfitting under 10 CFR part 50, 70, or 76 and would not otherwise be inconsistent with the issue finality provisions under 10 CFR part 52. As discussed in the “Implementation” section of the DG, the NRC has no current intention to impose the DG, if finalized, on current holders of 10 CFR part 50 operating licenses or construction permits, 10 CFR part 52 combined licenses or early site permits, 10 CFR part 70 licenses, or 10 CFR part 76 certificates of compliance or approved compliance plans.

The DG, if finalized, could be applied to applicants for 10 CFR part 50 operating licenses or construction permits for power reactors, 10 CFR part 52 combined licenses or early site permits, licenses issued under 10 CFR part 70, or 10 CFR part 76 certificates of compliance or approved compliance plans. Such action would not constitute backfitting as defined under § 50.109, § 70.76, or § 76.76, or be otherwise inconsistent with the applicable issue finality provisions under 10 CFR part 52, inasmuch as such applicants are not within the scope of entities protected by § 50.109, § 70.76, § 76.76, or the relevant issue finality provisions under 10 CFR part 52, except in one circumstance. The exception to this principle is a combined license, early site permit, or construction permit applicant that has been issued an LWA, if the LWA authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA. However, that exception would provide backfitting and issue finality protection for the LWA holder only to the extent that it conducts activities under the LWA.

IX. Cumulative Effects of Regulation

The NRC seeks to minimize any potential negative consequences resulting from the cumulative effects of regulation (CER). The CER describes the challenges that licensees, or other impacted entities such as State partners, may face while implementing new regulatory positions, programs, or requirements (e.g., rules, generic letters, backfits, inspections). The CER is an organizational effectiveness challenge

that may result from a licensee or impacted entity implementing a number of complex regulatory positions, programs, or requirements within limited available resources.

In an effort to better understand the potential CER implications incurred due to this proposed rule, the NRC is requesting comment on the following questions. Responding to these questions is voluntary, and the NRC will respond to any comments received in the final rule.

1. In light of any current or projected CER challenges, does the proposed rule's effective date provide sufficient time to implement the new proposed requirements, including changes to programs, procedures, and the facility?

2. If current or projected CER challenges exist, what should be done to address this situation? For example, if more time is required for implementation of the new requirements, what period of time is sufficient?

3. Do other regulatory actions (from the NRC or other agencies) influence the implementation of the proposed rule's requirements?

4. Are there unintended consequences? Does the proposed rule create conditions that would be contrary to the proposed rule's purpose and objectives? If so, what are the unintended consequences, and how should they be addressed?

5. Please comment on the NRC's cost and benefit estimates in the regulatory analysis that supports the proposed rule.

X. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, “Plain Language in Government Writing,” published June 10, 1998 (63 FR 31885). The NRC requests comment on this document with respect to the clarity and effectiveness of the language used.

XI. Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed rule is the type of action described under § 51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed rule.

XII. Paperwork Reduction Act Statement

This proposed rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This proposed rule has been submitted to the Office of Management and Budget (OMB) for review and approval of the information collection(s).

Type of submission, new or revision: Revision.

The title of the information collection: 10 CFR part 26, Fitness for Duty Drug Testing Requirements.

The form number if applicable: Not applicable.

How often the collection is required: Once and annually. One-time information collections include the licensee or other entity of each FFD program completing revisions to the FFD program policy and FFD procedures, to distribute information on the FFD program policy updates to individuals subject to 10 CFR part 26, and for those subject individuals to review the information on the FFD program policy changes. Annual information collections include the licensee or other entity of each FFD program submitting an FFD program performance report to the NRC to provide information on the additional positive drug test results that would result from the proposed rule changes. On occasion, a third party disclosure would be made for each additional positive drug test result from the proposed rule changes. Also, on occasion, the licensee or other entity would report information to the NRC in the form of a 24-hour event report when some individuals (e.g., licensed reactor operators, supervisors) test positive as a result of the proposed rule changes.

Who will be required or asked to report: Licensees of nuclear power reactor sites (operating and under construction), licensees of Category I fuel cycle facilities, contractors/vendors, HHS-certified laboratories, and individuals with a positive drug test result.

An estimate of the number of annual responses: 7,813 (33 recordkeepers + 68 reporting responses + 7,712 third-party disclosures).

The estimated number of annual respondents: 149 (27 FFD programs, 12 HHS-certified laboratories, 6 licensee testing facilities, and 104 individuals with a positive drug test result).

An estimate of the total number of hours needed annually to complete the requirement or request: 1,382 (559 hours recordkeeping + 71 hours reporting + 752 hours third-party disclosure).

Abstract: 10 CFR part 26 contains the NRC's requirements for licensee and other entity FFD programs, which focus on preventing and detecting the impairment of personnel from the misuse of legal drugs and alcohol, use of illegal drugs, fatigue, and any other causes such as mental or psychological distress. The NRC is seeking to update the drug testing panel and to lower the testing cutoff levels for some drugs tested, which would impact the information collections contained in 10 CFR part 26, because additional individuals would likely test positive for drugs. The expected additional positive test results would increase the recordkeeping and reporting burdens on licensees and other entities. The NRC is proposing to include new information collection requirements in §§ 26.107(d), 26.157(a), 26.165(b)(2) and (b)(3), 26.165(f)(1) and 26.185(f)(3). This information is needed to uniformly address subversion attempts identified at the collection site (§ 26.107(d)), clarify that HHS-certified laboratories are to maintain testing procedures specific to 10 CFR part 26 (§ 26.157(a)), permit the MRO to initiate retesting of a donor specimen upon receiving an oral request from the donor and maintaining a record of receiving that request (§ 26.165(b)(2) and (b)(3)), document the existing process that the MRO is to report a cancelled test result to the licensee or other entity if the results of specimen retesting fail to confirm the test results from the initial laboratory (§ 26.165(f)(1)), and establish procedures to review invalid specimen test results due to high pH values (§ 26.165(f)(3)).

The NRC is seeking public comment on the potential impact of the information collection(s) contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

2. Is the estimate of burden of the proposed information collection accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the proposed information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the OMB clearance package and proposed rule is available in ADAMS under Accession No. ML16123A003 or may be viewed free of

charge at the NRC's PDR, One White Flint North, 11555 Rockville Pike, Room O-1 F21, Rockville, MD 20852. You may obtain information and comment submissions related to the OMB clearance package by searching on <https://www.regulations.gov> under Docket ID NRC-2009-0225.

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

- **Federal rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID NRC-2009-0225.

- **Mail comments to:** Information Services Branch: T6-A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by email to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0146), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: oira_submission@omb.eop.gov.

Submit comments by October 16, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC staff is able to ensure consideration only for comments received on or before this date.

Public Protection Notification

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

XIII. Compatibility of Agreement State Regulations

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the **Federal Register** (62 FR 46517; September 3, 1997), this rule is classified as compatibility "NRC." Compatibility is not required for Category "NRC" regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the AEA or the provisions of title 10 of the *Code of Federal Regulations*, and although an Agreement State may not adopt program elements reserved to the NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws but does not confer regulatory authority on the State.

XIV. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC is proposing to update and enhance the consistency of 10 CFR part 26 with the 2008 HHS Guidelines; improve the effectiveness and efficiency of FFD programs with regard to drug testing; and improve clarity in the organization and language of the rule.

This action would not constitute the establishment of a voluntary consensus standard that contains generally applicable requirements.

XV. Availability of Guidance

The NRC is issuing for comment new draft regulatory guidance, Draft Regulatory Guide DG-5040, "Urine Specimen Collection and Test Result Review under 10 CFR Part 26, Fitness for Duty Programs," to support the implementation of the proposed requirements in this rulemaking. You may access information and comment submissions related to the DG by searching on <https://www.regulations.gov> under Docket ID NRC-2009-0225. Comments on the DG may be submitted to the NRC as indicated under the **ADDRESSES** caption of this document.

The guidance describes methods that the NRC would consider acceptable for complying with some of the proposed changes in this notice. For example, guidance would be provided concerning monitoring of a donor during the 3-hour hydration period, use of reflective mirrors for directly observed collections, use of a same-gender observer other than the collector during a directly observed collection, and MRO review of invalid test results due to high pH.

XVI. Availability of Documents

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

Document	ADAMS Accession No./ Federal Register citation
1988 HHS Guidelines—Final Guidelines (April 11, 1988)	53 FR 11970
1994 HHS Guidelines—Revised Mandatory Guidelines (June 9, 1994)	59 FR 29908
1998 HHS Guidelines—Revised Mandatory Guidelines (November 13, 1998)	63 FR 63483
2004 HHS Guidelines—Notice of Proposed Revisions to Mandatory Guidelines (April 13, 2004)	69 FR 19673
2004 HHS Guidelines—Revised Mandatory Guidelines (April 13, 2004)	69 FR 19643
2008 HHS Guidelines—Revised Mandatory Guidelines (November 25, 2008)	73 FR 71858
2008 HHS Guidelines—Revised Mandatory Guidelines, Correction of Effective Date (December 10, 2008)	73 FR 75122
2008 HHS Guidelines—Revised Mandatory Guidelines, Change in Effective Date (April 30, 2010)	75 FR 22809
2017 HHS Guidelines—Revised Mandatory Guidelines (January 23, 2017)	82 FR 7920
1989 NRC 10 CFR Part 26 final rule (June 7, 1989)	54 FR 24468
1993 NRC 10 CFR Part 26 final rule (June 3, 1993)	58 FR 31467
2008 NRC 10 CFR Part 26 final rule (March 31, 2008)	73 FR 16966
2009 NRC 10 CFR Part 26 final rule, correcting amendment (August 3, 2009)	74 FR 38326
Policy Statement on Adequacy and Compatibility of Agreement State Programs (September 3, 1997)	62 FR 46517
Presidential Memorandum, "Plain Language in Government Writing" (June 10, 1998)	63 FR 31885
2001 DOT 49 CFR Part 40 final rule, Procedures for Transportation Workplace Drug and Alcohol Testing Programs; Technical Amendments (August 9, 2001).	66 FR 41944
2010 DOT 49 CFR Part 40 final rule, Procedures for Transportation Workplace Drug and Alcohol Testing Programs (August 16, 2010).	75 FR 49850
2014 National Drug Control Strategy (July 9, 2014)	ML19169A230
Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health (September 2015), HHS Publication No. SMA 15-4927.	ML19169A160
Commission Policy Statement on Fitness for Duty of Nuclear Power Plant Personnel (August 4, 1986)	51 FR 27921

Document	ADAMS Accession No./ Federal Register citation
Cook J.D., Strauss K.A., Caplan Y.H., LoDico C.P., and Bush D.M. (2007), "Urine pH: the effects of time and temperature after collection," <i>Journal of Analytical Toxicology</i> , Vol. 31, 486–496.	ML19169A178
Executive Order 12564 (September 17, 1986)	51 FR 32889
NRC Draft Regulatory Guide DG-5040, "Urine Specimen Collection and Test Result Review under 10 CFR Part 26, 'Fitness for Duty Programs'" (August 2019).	ML19116A077
NRC Enforcement Guidance Memorandum—Dispositioning Violations of NRC Requirements for Initial Validity and Drug Tests at Licensee Testing Facilities (EGM-09-003) (March 31, 2009).	ML090760728
NRC Public Meeting Summary (February 24, 2009)	ML090771060
NRC Public Meeting Summary (June 24, 2009)	ML091910511
NRC Public Meeting Summary and Meeting Materials (October 11, 2011)	ML112930153
NRC Public Meeting Summary (September 11, 2013)	ML13290A236
NRC Regulatory Analysis and Backfit Analysis, Fitness For Duty Drug Testing Requirements (August 2019)	ML19169A115
NRC Regulatory Analysis Guidelines, NUREG/BR-0058, Revision 4 (September 30, 2004)	ML042820192
NRC Regulatory Basis: Proposed Rulemaking to Amend 10 CFR Part 26, "Fitness for Duty Programs," based on Select Provisions of the 2008 HHS Guidelines (May 10, 2013).	ML13066A703
NRC report "Summary of Fitness for Duty Program Performance Reports for Calendar Year 2013" (September 3, 2014)	ML14246A440
NRC report "Summary of Fitness for Duty Program Performance Reports for Calendar Year 2012" (August 13, 2013)	ML13225A131
NRC report "Summary of Fitness for Duty Program Performance Reports for Calendar Year 2011" (August 1, 2012)	ML12151A270
Quest Diagnostics (2011). Impacts of Panel Changes—The First Three Months (January 25, 2011)	ML19169A153
Quest Diagnostics (2012). Cocaine Positives Spike 33% After New Government Rule for Safety-Sensitive Workers (March 13, 2012).	ML19169A156
Quest Diagnostics (2014). Workforce Drug Test Positivity Rate Increases for the First Time in 10 Years, Driven by Marijuana and Amphetamines, Finds Quest Diagnostics Drug Testing Index™ Analysis of Employment Drug Tests (Press Release and Drug Testing Index, 2014 Report) (September 11, 2014).	ML19169A147

List of Subjects in 10 CFR Part 26

Administrative practice and procedure, Alcohol abuse, Alcohol testing, Appeals, Chemical testing, Drug abuse, Drug testing, Employee assistance programs, Fitness for duty, Management actions, Nuclear power plants and reactors, Privacy, Protection of information, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553 the NRC is proposing to adopt the following amendments to 10 CFR part 26:

PART 26—FITNESS FOR DUTY PROGRAMS

- 1. The authority citation for part 26 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 103, 104, 107, 161, 223, 234, 1701 (42 U.S.C. 2073, 2133, 2134, 2137, 2201, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); 44 U.S.C. 3504 note.

- 2. Amend part 26, wherever they may occur by:

- a. Removing the term "custody-and-control form" and adding in its place the term "Federal CCF";
- b. Removing the term "custody-and-control forms" and adding in its place the term "Federal CCFs."

- c. Removing the term "custody-and-control form(s)" and adding in its place the term "Federal CCF(s)"; and

- d. Removing the phrase "chain-of-custody" and adding in its place the phrase "chain of custody".

- 3. Amend § 26.4 by:

- a. Removing in paragraph (e)(6)(iv), the phrase "(65 FR 41944; August 9, 2001)";

- b. Removing in paragraph (g)(4), word "and" at the end;

- c. Removing in paragraph (g)(5), the period at the end and add in its place "; and";

- d. Adding new paragraph (g)(6); and

- e. Revising paragraph (j)(3).

The additions and revisions read as follows:

§ 26.4 FFD program applicability to categories of individuals.

* * * * *

(g) * * *

(6) All persons monitoring a donor during the hydration process described in § 26.109(b).

* * * * *

(j) * * *

(3) Urine specimens are tested for validity and the presence of drugs and drug metabolites at a Department of Health and Human Services (HHS)-certified laboratory, as defined in § 26.5;

* * * * *

- 4. Amend § 26.5 by:

- a. Adding the definitions for *cancelled test*, *carryover*, *Certifying Scientist*, *Federal custody and control form* (*Federal CCF*), *lot*, *rejected for testing*,

and *Responsible Person* in alphabetical order; and

- b. Revising the definitions for *calibrator*, *control*, *dilute specimen*, *HHS-certified laboratory*, *invalid result*, *limit of quantitation*, and *substituted specimen*.

The additions and revisions read as follows:

§ 26.5 Definitions.

* * * * *

Calibrator means a solution of known concentration in the appropriate matrix that is used to define expected outcomes of a measurement procedure or to compare the response obtained with the response of a donor specimen or quality control sample. The concentration of the analyte of interest in the calibrator is known within limits ascertained during its preparation.

* * * * *

Cancelled test means the test result reported by the MRO to the licensee or other entity when a specimen has been reported to the MRO by the HHS-certified laboratory as an invalid result (for which the donor has no legitimate explanation), a specimen has been rejected for testing by the licensee testing facility or HHS-certified laboratory, or the retesting of a single specimen or the testing of Bottle B of a split specimen fails to reconfirm the original test result. For alcohol testing only, *cancelled test* means a test result that was not acceptable because testing

did not meet the quality assurance and quality control requirements in § 26.91.

Carryover means the effect that occurs when a test result has been affected by a preceding sample or specimen during analysis.

Certifying Scientist means the individual at an HHS-certified laboratory responsible for verifying the chain of custody and scientific reliability of any test result reported by an HHS-certified laboratory.

Control means a sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

Dilute specimen means a urine specimen with creatinine and specific gravity values that are lower than expected but are still within the physiologically producible ranges of human urine.

Federal custody and control form (Federal CCF) means any HHS-approved form, which has not expired, that is published in the **Federal Register** and is used to document the collection, custody, transport, and testing of a specimen.

HHS-certified laboratory means a laboratory that is certified to meet the standards of the *Mandatory Guidelines for Federal Workplace Drug Testing Programs* (the HHS Guidelines) at the time that drug and validity testing of a specimen is performed for a licensee or other entity.

Invalid result means the result reported by an HHS-certified laboratory in accordance with the criteria established in § 26.161(f) when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test.

Limit of quantitation (LOQ) means for quantitation assays, the lowest concentration at which the identity and concentration of the analyte can be accurately established.

Lot means a number of units of an item (e.g., drug test kits, reagents, quality control samples) manufactured from the same starting materials within a specified period of time for which the manufacturer states that the items have essentially the same performance

characteristics and the same expiration date.

Rejected for testing means the result reported to the MRO by a licensee testing facility or HHS-certified laboratory when no tests can be performed on a specimen.

Responsible Person means the person at the HHS-certified laboratory who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory.

Substituted specimen means a specimen that has been submitted in place of the donor's urine, as evidenced by creatinine and specific gravity values that are outside the physiologically producible ranges of human urine.

§ 26.8 [Amended]

- 5. In § 26.8, remove the reference “26.155” in paragraph (b).
- 6. Amend § 26.31 by:
 - a. Removing in paragraph (b)(2) the phrase “(65 FR 41944; August 9, 2001)”;
 - b. Revising paragraph (d)(1) introductory text;
 - c. Removing in paragraph (d)(1)(i)(D) the phrase “, as specified in § 26.155(a)” at the end of the second sentence; and
 - d. Revising in paragraph (d)(1)(ii) the third sentence.

The revisions read as follows:

§ 26.31 Drug and alcohol testing.

(d) * * *

(1) *Substances tested.* At a minimum, licensees and other entities shall test for marijuana metabolite, cocaine metabolite, opiates (codeine, morphine, and 6-acetylmorphine), amphetamines (amphetamine, methamphetamine, methylenedioxymethamphetamine, and methylenedioxymphetamine), phencyclidine, adulterants, and alcohol.

(ii) * * * Test results that fall below the established cutoff levels may not be considered when determining appropriate action under subpart D of this part, except if special analyses of the specimen is performed under § 26.163(a)(2) by the HHS-certified laboratory.

- 7. Amend § 26.89 by:
 - a. Removing in paragraph (c) in the first sentence, the words “adulterated, diluted, or adulterated the specimen” and adding in its place the words “adulterated, diluted, or substituted the specimen”; and

- b. Revising paragraph (d) to read as follows:

§ 26.89 Preparing to collect specimens for testing.

(d) In order to promote the security of specimens, avoid distraction of the collector, and ensure against any confusion in the identification of specimens, a collector shall conduct only one collection procedure at any given time, except as described in § 26.109(b)(1). The urine collection procedure is complete when the urine specimen container has been sealed with tamper-evident tape, the seal has been dated and initialed, and the Federal CCF has been completed or when a refusal to test has been determined under § 26.107(d).

- 8. In § 26.107, revise paragraph (b) and add paragraph (d) to read as follows:

§ 26.107 Collecting a urine specimen.

(b)(1) The collector shall pay attention to the donor during the entire collection process, except as provided in § 26.109(b)(1), to observe any conduct that indicates an attempt to subvert the testing process (e.g., tampering with a specimen; having a substitute urine in plain view; attempting to bring an adulterant, urine substitute, heating element, and/or temperature measurement device into the room, stall, or private area used for urination). If any such conduct is detected, the collector shall document a description of the conduct on the Federal CCF and contact FFD program management to determine whether a directly observed collection is required, as described in § 26.115.

(2) If a hydration monitor is used to observe a donor during the § 26.109(b)(1) hydration process, this individual shall immediately inform the collector of any donor conduct that may indicate an attempt to subvert the testing process (e.g., donor leaves the collection site, donor refuses to follow instructions).

(d) If a refusal to test is determined at any point during the specimen collection process, the collector shall do the following:

- (1) Inform the donor that a refusal to test has been determined;
- (2) Terminate the collection process;
- (3) Document a description of the refusal to test on the Federal CCF;
- (4) Discard any urine specimen(s) provided by the donor, unless the specimen was collected for a post-event test under § 26.31(c)(3); and

(5) Immediately inform the FFD program manager.

■ 9. In § 26.109, revise paragraph (b)(1) and add a new first sentence to paragraph (b)(2) to read as follows:

§ 26.109 Urine specimen quantity.

* * * * *

(b) * * *

(1) The collector shall encourage the donor to drink a reasonable amount of liquid (normally, 8 ounces of water every 30 minutes, but not to exceed a maximum of 40 ounces over 3 hours) until the donor provides a specimen of at least 30 mL. Alternatively, as specified in the licensee's or other entity's FFD program procedures, the collector may assign responsibility for monitoring a donor during the hydration process to another collector who meets the requirements in § 26.85(a) or to a hydration monitor who meets the requirements in § 26.4(g)(6). If another collector or hydration monitor is used, the collector:

(i) Shall explain the hydration process and acceptable donor behavior to the hydration monitor;

(ii) Shall record the name of the other collector or hydration monitor on the Federal CCF and then provide the Federal CCF to that individual for the duration of the hydration process; and

(iii) May perform other collections while the donor is in the hydration process;

(2) The collector shall provide the donor with a separate collection container for each successive specimen.

* * *

* * * * *

■ 10. Amend § 26.111 by:

■ a. Revising paragraph (a);

■ b. Removing in paragraph (c) the first sentence the word "designated" and revising the third sentence;

■ c. Revising paragraph (e); and

■ d. Removing paragraph (f).

The revisions read as follows:

§ 26.111 Checking the acceptability of the urine specimen.

(a) Immediately after the donor provides the urine specimen to the collector, including specimens of less than 30 mL but equal to or greater than 15 mL, the collector shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement may not exceed 4 minutes. If the temperature of a urine specimen is outside the range of 90 °F to 100 °F (32 °C to 38 °C), that is a reason to believe the donor may have

altered (e.g., adulterated or diluted) or substituted the specimen.

* * * * *

(c) * * * In addition, the collector shall inform the donor that he or she may volunteer to submit a second specimen under direct observation to counter the reason to believe the donor may have altered (e.g., adulterated or diluted) or substituted the specimen.

* * * * *

(e) As much of the suspect specimen as possible must be preserved, except under the conditions described in § 26.107(d)(4).

■ 11. Amend § 26.115 by:

■ a. Republishing paragraph (a) introductory text, revising paragraphs (a)(3) and (4), and adding paragraph (a)(5);

■ b. Revising paragraph (e);

■ c. Revising paragraph (f) introductory text, republishing paragraph (f)(1), and revise paragraphs (f)(2) and (3); and

■ d. Revising paragraph (g).

The additions and revisions read as follows:

§ 26.115 Collecting a urine specimen under direct observation.

(a) Procedures for collecting urine specimens must provide for the donor's privacy unless directed by this subpart or the MRO or FFD program manager determines that a directly observed collection is warranted. The following circumstances constitute the exclusive grounds for performing a directly observed collection:

* * * * *

(3) The collector, or the hydration monitor if one is used as permitted in § 26.109(b)(1), observes conduct by the donor indicating an attempt to subvert the testing process;

(4) A directly observed collection is required under § 26.69; or

(5) The donor requests a retest and either Bottle B or the single specimen is not available due to circumstances outside of the donor's control, as described in § 26.165(f)(2).

* * * * *

(e) The collector shall ensure that the observer is the same gender as the donor. A person of the opposite gender may not act as the observer under any conditions. The observer may be a different person from the collector and need not be a qualified collector. If the observer is not a qualified collector, the collector shall, in the presence of the donor, instruct the observer on the collection procedures in paragraph (f) of this section before proceeding with the directly observed collection.

(f) The individual who observes the collection shall follow these procedures:

(1) The observer shall instruct the donor to adjust his or her clothing to ensure that the area of the donor's body between the waist and knees is exposed;

(2) The observer shall watch the donor urinate into the collection container. Specifically, the observer shall watch the urine go from the donor's body into the collection container. A reflective mirror may be used to assist in observing the provision of the specimen only if the physical configuration of the room, stall, or private area is not sufficient to meet this direct observation requirement; the use of a video camera to assist in the observation process is not permitted;

(3) If the observer is not the collector, the observer may not touch or handle the collection container but shall maintain visual contact with the specimen until the donor hands the collection container to the collector; and

* * * * *

(g) If a donor declines to allow a directly observed collection that is required or permitted under this section, the donor's refusal constitutes an act to subvert the testing process, and the collector shall follow the procedures in § 26.107(d).

* * * * *

■ 12. Amend § 26.117 by:

■ a. Revising paragraph (a);

■ b. Revising the first sentence in paragraph (f); and

■ c. Adding in paragraph (g) the phrase "except as provided in § 26.109(b)(1)(ii) for the Federal CCF" to the end of the first sentence.

The revisions read as follows:

§ 26.117 Preparing urine specimen for storage and shipping

(a) Once the collector is presented with the specimen from the donor, both the donor and the collector shall keep the donor's urine specimen(s) in view at all times before the specimen(s) are sealed and labeled. If any specimen or aliquot is transferred to another container, the collector shall ask the donor to observe the transfer and sealing of the container with a tamper-evident seal.

* * * * *

(f) The specimens and Federal CCFs must be packaged for transfer to the HHS-certified laboratory or to the licensee testing facility. * * *

* * * * *

■ 13. In § 26.129, revise paragraphs (b)(1)(ii) and (b)(2) introductory text to read as follows:

§ 26.129 Assuring specimen security, chain of custody, and preservation.

* * * * *

(b) * * *

(1) * * *

(ii) If there is reason to believe that the integrity or identity of a specimen is in question (as a result of tampering or discrepancies between the information on the specimen bottle and on the accompanying Federal CCFs that cannot be resolved), the licensee testing facility shall reject the specimen for testing. The licensee or other entity shall ensure that another collection occurs as soon as reasonably practical, except if a split specimen collection was performed, either the Bottle A or Bottle B seal remains intact, and the intact specimen contains at least 15 mL of urine. In this instance, the licensee testing facility shall forward the intact specimen for testing to the HHS-certified laboratory and may not conduct any testing at the licensee testing facility.

(2) The following are exclusive grounds requiring the MRO to cancel the testing of a donor's urine specimen and report a cancelled test result to the licensee or other entity:

* * * * *

■ 14. Revise § 26.133 to read as follows:

§ 26.133 Cutoff levels for drugs and drug metabolites.

Subject to the provisions of § 26.31(d)(3)(iii), licensees and other entities may specify more stringent cutoff levels for drugs and drug metabolites than those in the table below and, in such cases, may report initial test results for only the more stringent cutoff levels. Otherwise, the following cutoff levels must be used for initial testing of urine specimens to determine whether they are negative or positive for the indicated drugs and drug metabolites:

**INITIAL TEST CUTOFF LEVELS FOR
DRUGS AND DRUG METABOLITES**

Drugs or drug metabolites	Cutoff level [nanograms (ng)/mL]
Marijuana metabolites	50
Cocaine metabolites	150
Opiate metabolites:	
Codeine/Morphine ¹	2000
6-acetylmorphine (6-AM)	10
Phencyclidine (PCP)	25
Amphetamines: ²	
AMP/MAMP ³	500
MDMA ⁴ /MDA ⁵	500

¹ Morphine is the target analyte for codeine/morphine testing.

² Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.

³ Methamphetamine (MAMP) is the target analyte for amphetamine (AMP)/MAMP testing.

⁴ Methylenedioxymethamphetamine.

⁵ Methylenedioxymphetamine.

■ 15. In § 26.137, revise paragraphs (d)(5), (e)(6)(i) through (iii), and (e)(6)(v) to read as follows:

§ 26.137 Quality assurance and quality control.

* * * * *

(d) * * *

(5) Each analytical run performed to conduct initial validity testing shall include at least one quality control sample that appears to be a normal specimen to the licensee testing facility technicians.

* * * * *

(e) * * *

(6) A minimum of 10 percent of the total specimens in each analytical run of specimens to be initially tested for drugs and drug metabolites by the licensee testing facility must be quality control samples (*i.e.*, calibrators and controls), which the licensee testing facility shall use for internal quality control purposes. (These samples are not forwarded to the HHS-certified laboratory for further testing, other than for performance testing of the samples.) Licensee testing facilities shall ensure that quality control samples that are positive for each drug and drug metabolite for which the FFD program conducts testing are included in at least one analytical run each calendar quarter. The quality control samples for each analytical run must include—

(i) At least one control certified by an HHS-certified laboratory to contain no drug or drug metabolite;

(ii) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff;

(iii) At least one positive control with the drug or drug metabolite targeted at 75 percent of the cutoff;

* * * * *

(v) At least one quality control sample that appears to be a normal specimen to the licensee testing facility technicians.

* * * * *

■ 16. In § 26.153, revise paragraphs (a) and (g) to read as follows:

§ 26.153 Using certified laboratories for testing urine specimens.

(a) Licensees and other entities who are subject to this part shall use only HHS-certified laboratories as defined in § 26.5.

* * * * *

(g) If licensees or other entities use a form other than the current Federal CCF, licensees and other entities shall provide a memorandum to the laboratory explaining why a non-Federal CCF was used, but must ensure, at a minimum, that the form used contains all the required information on the Federal CCF.

§ 26.155 [Removed and Reserved]

■ 17. Remove and reserve § 26.155.

■ 18. Amend § 26.157 by:

■ a. Revising paragraph (a),

■ b. Removing and reserving paragraph (b), and removing paragraphs (c) through (e).

The revisions read as follows:

§ 26.157 Procedures.

(a) HHS-certified laboratories shall develop, implement, and maintain procedures specific to this part that document the accession, receipt, shipment, and testing of specimens.

(b) [Reserved]

■ 19. In § 26.159, revise paragraphs (b)(1)(ii), (b)(2) introductory text, the second sentence in paragraph (c), and paragraphs (d) and (e) to read as follows:

§ 26.159 Assuring specimen security, chain of custody, and preservation.

* * * * *

(b) * * *

(1) * * *

(ii) If the licensee or other entity has reason to question the integrity and identity of the specimens, the laboratory shall reject the specimens for testing. The licensee or other entity shall ensure that another collection occurs as soon as reasonably practical, except if a split specimen collection was performed, either the Bottle A or Bottle B seal remains intact, and the intact specimen contains at least 15 mL of urine. In this instance, if the licensee testing facility has retained the specimen in Bottle B, the licensee testing facility shall forward the intact specimen for testing to the HHS-certified laboratory and may not conduct any testing at the licensee testing facility.

(2) The following are exclusive grounds requiring the MRO to cancel the testing of a donor's urine specimen and report a cancelled test to the licensee or other entity:

* * * * *

(c) * * * Laboratory personnel shall use aliquots and laboratory internal chain of custody forms when conducting initial and confirmatory tests. * * *

(d) The laboratory's internal chain of custody form must allow for identification of the donor and documentation of the testing process and transfers of custody of the specimen.

(e) Each time a specimen is handled or transferred within the laboratory, laboratory personnel shall document the date and purpose on the chain of custody form and every individual in the chain shall be identified. Authorized technicians are responsible for each urine specimen or aliquot in their

possession and shall sign and complete chain of custody forms for those specimens or aliquots as they are received.

* * * *

■ 20. Amend § 26.161 by:

- a. Removing in paragraphs (c)(3) and (c)(4), (f)(5), and (f)(7) the term “LOD” and adding in its place the term “LOQ”; and
- b. Revising paragraphs (c)(5) and (c)(6).

The revisions read as follows:

§ 26.161 Cutoff levels for validity testing.

* * * *

(c) * * *

(5) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and a different confirmatory test (e.g., gas chromatography/mass spectrometry (GC/MS)) for the confirmatory test with the glutaraldehyde concentration equal to or greater than the LOQ of the analysis on the second aliquot;

(6) The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff or an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (e.g., GC/MS) for the confirmatory test with the pyridine concentration equal to or greater than the LOQ of the analysis on the second aliquot;

* * * *

■ 21. Amend § 26.163 by:

- a. Republishing paragraph (a) introductory text,
- b. Revising paragraphs (a)(1), (a)(2) introductory text, (a)(2)(i), and (ii),
- c. Republishing paragraph (b) introductory text, and
- d. Revising paragraph (b)(1).

The revisions read as follows:

§ 26.163 Cutoff levels for drugs and drug metabolites.

(a) *Initial drug testing.* (1) HHS-certified laboratories shall apply the following cutoff levels for initial testing of specimens to determine whether they are negative or positive for the indicated drugs and drug metabolites, except as specified in paragraph (a)(2) of this section or the licensee or other entity has established more stringent cutoff levels:

INITIAL TEST CUTOFF LEVELS FOR DRUGS AND DRUG METABOLITES

Drugs or drug metabolites	Cutoff level [nanograms (ng)/mL]
Marijuana metabolites	50
Cocaine metabolites	150
Opiate metabolites:	
Codeine/Morphine ¹	2000
6-acetylmorphine (6-AM)	10
Phencyclidine (PCP)	25
Amphetamines: ²	
AMP/MAMP ³	500
MDMA ⁴ /MDA ⁵	500

¹ Morphine is the target analyte for codeine/morphine testing.

² Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.

³ Methamphetamine (MAMP) is the target analyte for amphetamine (AMP)/MAMP testing.

⁴ Methylenedioxymethamphetamine.

⁵ Methylenedioxyamphetamine.

(2) HHS-certified laboratories shall conduct special analyses of specimens as follows:

(i) If initial validity testing indicates that a specimen is dilute, or if a specimen is collected under direct observation for any of the conditions specified in § 26.115(a)(1) through (a)(3) or (a)(5), the laboratory shall compare the immunoassay responses of the specimen to the cutoff calibrator in each drug class tested;

(ii) If any immunoassay response is equal to or greater than 40 percent of the cutoff calibrator, the laboratory shall conduct confirmatory drug testing of the specimen to the LOQ for those drugs and/or drug metabolites; and

* * * *

(b) *Confirmatory drug testing.* (1) A specimen that is identified as positive on an initial drug test must be subject to confirmatory testing for the class(es) of drugs for which the specimen initially tested positive. The HHS-certified laboratory shall apply the confirmatory cutoff levels specified in this paragraph, except as permitted in paragraph (a)(2) of this section or the licensee or other entity has established more stringent cutoff levels.

CONFIRMATORY TEST CUTOFF LEVELS FOR DRUGS AND DRUG METABOLITES

Drugs or drug metabolites	Cutoff level (ng/mL)
Marijuana metabolite ¹	15
Cocaine metabolite ²	100
Opiate metabolites:	
Morphine	2000
Codeine	2000
6-acetylmorphine (6-AM)	10
Phencyclidine (PCP)	25
Amphetamines:	
Amphetamine	250
Methamphetamine ³	250
MDMA	250

CONFIRMATORY TEST CUTOFF LEVELS FOR DRUGS AND DRUG METABOLITES—Continued

Drugs or drug metabolites	Cutoff level (ng/mL)
MDA	250

¹ As delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).

² As benzoylecgonine.

³ To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.

* * * *

■ 22. In § 26.165, revise the fourth sentence in paragraph (b)(2), paragraph (b)(3), the last sentence in paragraph (f)(1) introductory text, and paragraph (f)(2) to read as follows:

§ 26.165 Testing split specimens and retesting single specimens.

* * * *

(b) * * *

(2) * * * The MRO shall document in his or her records when (i.e., date and time) the request was received from the donor to retest an aliquot of the single specimen or to test the Bottle B split specimen.

(3) No entity, other than the MRO as permitted in § 26.185(l), may order the retesting of an aliquot of a single specimen or the testing of the Bottle B split specimen.

* * * *

(f) * * *

(1) * * * If the results of testing Bottle B or retesting the aliquot of a single specimen are negative, the MRO shall report a cancelled test result to the licensee or other entity, and the licensee and other entity—

* * * *

(2) If a donor requests that Bottle B be tested or that an aliquot of a single specimen be retested, and either Bottle B or the single specimen are not available due to circumstances outside of the donor's control (including, but not limited to, circumstances in which there is an insufficient quantity of the single specimen or the specimen in Bottle B to permit retesting, either Bottle B or the original single specimen is lost in transit to the second HHS-certified laboratory, or Bottle B has been lost at the HHS-certified laboratory or licensee testing facility), the MRO shall cancel the test, report a cancelled test result to the licensee or other entity for the donor's specimen, and inform the licensee or other entity that another collection is required under direct observation as soon as reasonably practical. The donor shall receive no notice of the collection requirement before he or she is instructed to proceed to the collection site. The licensee or

other entity shall continue to administratively withdraw the individual's authorization, as required by § 26.165(f)(1) until the results of the second specimen collection have been received by the MRO. The licensee or other entity shall eliminate from the donor's personnel and other records any matter that could link the donor to the original positive, adulterated, or substituted test result(s) and any temporary administrative action, and may not impose any sanctions on the donor for a cancelled test. If test results from the second specimen collected are positive, adulterated, or substituted and the MRO determines that the donor has violated the FFD policy, the licensee or other entity shall impose the appropriate sanctions specified in subpart D of this part, but may not consider the original confirmed positive, adulterated, or substituted test result that was reported as a cancelled test by the MRO under §§ 26.129(b)(2) or 26.159(b)(2) in determining the appropriate sanctions.

■ 23. Amend § 26.167 by:

- a. Republishing paragraph (d)(3) introductory text, and revising paragraphs (d)(3)(i) through (iii);
- b. Revising paragraph (d)(4);
- c. Revising paragraph (e)(2), republishing paragraph (e)(3) introductory text, and revising paragraphs (e)(3)(i) through (iv); and
- d. Removing in paragraph (f)(3) the third sentence, the words "responsible person" and adding in their place the words "Responsible Person".

The revisions read as follows:

§ 26.167 Quality assurance and quality control.

* * * * *

(d) * * *

(3) Quality control samples for each analytical run of specimens for initial testing must include—

- (i) At least one control certified to contain no drug or drug metabolite;
- (ii) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff;
- (iii) At least one positive control with the drug or drug metabolite targeted at 75 percent of the cutoff;

* * * * *

(4) A minimum of 10 percent of the total specimens in each analytical run must be quality control samples (*i.e.*, calibrators and controls), as defined by paragraphs (d)(3)(i) through (iv) of this section.

(e) * * *

(2) A minimum of 10 percent of the total specimens in each analytical run must be quality control samples (*i.e.*, calibrators and controls).

(3) Each analytical run of specimens that are subjected to confirmatory testing must include—

- (i) At least one control certified to contain no drug or drug metabolite;
- (ii) A calibrator with its drug concentration at the cutoff;
- (iii) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff; and
- (iv) At least one control targeted at or below 40 percent of the cutoff.

* * * * *

■ 24. In § 26.168, revise paragraph (h)(1) to read as follows:

§ 26.168 Blind performance testing.

* * * * *

(h) * * *

(1) Ensure that all blind performance test sample lots are placed in service by the supplier only after confirmation by an HHS-certified laboratory;

* * * * *

■ 25. Amend § 26.169 by:

- a. Removing in paragraph (a), wherever they may appear, the words "certifying scientist" and adding in their place the words "Certifying Scientist".
- b. Republishing paragraph (h)(3) introductory text, and revising paragraphs (h)(3)(i) and (ii), (h)(3)(iii)(C), and (h)(3)(iv);
- c. Republishing paragraph (h)(3)(v) introductory text and revising paragraph (h)(3)(v)(A); and
- d. Adding new paragraphs (h)(3)(v)(C) through (D).

The additions and revisions read as follows:

§ 26.169 Reporting results.

* * * * *

(h) * * *

(3) Number of specimens reported as positive on confirmatory tests by drug or drug metabolite for which testing is conducted, including, but not limited to—

- (i) Marijuana metabolite (as THCA);
- (ii) Cocaine metabolite (as benzoylecgonine);
- (C) 6-acetylmorphine (6-AM);
- (iv) Phencyclidine (PCP);
- (v) Amphetamines (total);
- (A) Amphetamine;

* * * * *

(C) Methylenedioxymethamphetamine (MDMA); and

(D) Methylenedioxyamphetamine (MDA);

* * * * *

■ 26. In § 26.183, revise paragraphs (c) introductory text, (c)(1), and (d)(2)(ii) to read as follows:

§ 26.183 Medical review officer.

* * * * *

(c) *Responsibilities.* The primary role of the MRO is to review and interpret positive, adulterated, substituted, invalid, and dilute test results obtained through the licensee's or other entity's testing program and to identify any evidence of subversion of the testing process. The MRO is also responsible for identifying any issues associated with collecting and testing specimens, and for advising and assisting FFD program management in planning and overseeing the overall FFD program.

(1) In carrying out these responsibilities, the MRO shall examine alternate medical explanations for any positive, adulterated, substituted, invalid, or dilute test result. This action may include, but is not limited to, conducting a medical interview with the donor, reviewing the donor's medical history, or reviewing any other relevant biomedical factors. The MRO shall review all medical records that the donor may make available when a positive, adulterated, substituted, invalid, or dilute test result could have resulted from responsible use of legally prescribed medication, a documented condition or disease state, or the demonstrated physiology of the donor.

* * * * *

(d) * * *

(2) * * *

(ii) The staff reviews of positive, adulterated, substituted, invalid, and dilute test results must be limited to reviewing the Federal CCF to determine whether it contains any errors that may require corrective action and to ensure that it is consistent with the information on the MRO's copy. The staff may resolve errors in Federal CCFs that require corrective action(s), but shall forward the Federal CCFs to the MRO for review and approval of the resolution.

* * * * *

■ 27. Amend § 26.185 by:

- a. Redesignating paragraph (f)(3) as (f)(4), and adding new paragraph (f)(3);
- b. Removing in paragraph (g)(1) the reference "paragraph (g)(4)" and adding in its place the reference "paragraph (g)(3)"; and
- c. Revising paragraphs (g)(2) introductory text and (g)(2)(iii), removing paragraph (g)(3), and redesignating paragraphs (g)(4) and (g)(5) as paragraphs (g)(3) and (g)(4), respectively.

The addition and revisions read as follows:

§ 26.185 Determining a fitness-for-duty policy violation.

* * * * *

(f) * * *

(3) If the MRO and the laboratory agree that further testing would not be useful and there is no legitimate technical or medical explanation, and the invalid result is based on pH in the range of 9.0 to 9.5, the MRO shall consider whether there is evidence of elapsed time, exposure of the specimen to high temperature, or both that could account for the pH value. If an acceptable explanation exists for the invalid test result due to pH, based on objective and sufficient information, that elapsed time, high temperature, or both caused the high pH and donor action did not result in the invalid pH result, the MRO shall report a cancelled test result to the licensee or other entity, cancel the test result, and direct the licensee or other entity to collect a second urine specimen from the donor as soon as reasonably practicable. The second specimen collected may not be collected under direct observation.

* * * * *

(g) * * *

(2) If the results of the special analysis testing required by § 26.163(a)(2) are positive, the MRO determines that there is no legitimate medical explanation for the presence of the drug(s) or drug metabolite(s) in the specimen, and a clinical examination, if required under paragraph (g)(3) of this section, has been

conducted under paragraph (j) of this section, the MRO shall determine whether the positive and dilute specimen is a refusal to test. If the MRO does not have sufficient reason to believe that the positive and dilute specimen is a subversion attempt, he or she shall determine that the drug test results are positive and that the donor has violated the FFD policy. When determining whether the donor has diluted the specimen in a subversion attempt, the MRO shall also consider the following circumstances, if applicable:

* * * * *

(iii) The collector observed conduct indicating an attempt to dilute the specimen.

* * * * *

■ 28. In § 26.405, revise paragraph (d) to read as follows:

§ 26.405 Drug and alcohol testing.

* * * * *

(d) At a minimum, licensees and other entities shall test specimens for marijuana metabolite, cocaine metabolite, opiates (codeine, morphine, and 6-acetylmorphine), amphetamines (amphetamine, methamphetamine, methylenedioxymethamphetamine, and methylenedioxyamphetamine), phencyclidine, adulterants, and alcohol at the cutoff levels specified in this part,

or comparable cutoff levels if specimens other than urine are collected for drug testing. Urine specimens collected for drug testing must be subject to validity testing.

* * * * *

§ 26.415 [Amended]

■ 29. In § 26.415 paragraph (c), remove the citation, “(65 FR 41944; August 9, 2001)”.

■ 30. In § 26.717, revise paragraphs (b)(3) and (4) to read as follows:

§ 26.717 Fitness-for-duty program performance data.

* * * * *

(b) * * *

(3) Populations tested (*i.e.*, licensee or other entity employees, C/Vs);

(4) Number of tests administered and results of those tests sorted by population tested (*i.e.*, licensee or other entity employees, C/Vs);

* * * * *

Dated at Rockville, Maryland, this 22nd day of August, 2019.

For the Nuclear Regulatory Commission.

Russell E. Chazell,

Acting Secretary of the Commission.

[FR Doc. 2019–18491 Filed 9–13–19; 8:45 am]

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