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Presidential Documents

Title 3—

Proclamation 10493 of November 8, 2022

The President

World Freedom Day, 2022

By the President of the United States of America

A Proclamation

On World Freedom Day, we remember the fall of the Berlin Wall and recall the hope felt around the world when freedom triumphed over tyranny. For decades, the Soviet Union ruled Central and Eastern Europe with an iron fist behind an Iron Curtain. But on that cold November night in 1989, the Berlin Wall fell, and East and West Berliners came together to send a clear message: the darkness that drives autocracy can never extinguish the flame of liberty that lights the souls of free people everywhere. Today, we reflect upon the power of people yearning for democracy and once again rededicate ourselves to the same cause.

Over the last 30 years, the forces of autocracy have been revived across the globe—exhibiting their contempt for the rule of law, for human rights and fundamental freedoms, and for truth itself. Russia's unjust war against Ukraine, and its attempts to forcibly claim territory through brutal violence and sham referenda, is the latest battle in a long struggle between liberty and repression—between a rules-based order and one governed by brute force. We are reminded once again that democracy is never guaranteed. We have to defend it, protect it, and stand up for it always.

The United States will be unabashed in promoting our vision of a free, open, secure, and prosperous world in the face of autocratic attempts to forge a darker path. The future will be won by countries where members of religious and ethnic minorities can live without harassment, where people can love freely without being targeted with violence, where privacy is respected and personal liberties are inalienable, and where citizens can vote freely and have that vote counted. We will continue investing in developing countries to help them drive down poverty, shore up critical infrastructure, and unleash the full potential of their populations. We will continue marshaling security, humanitarian, and economic support to Ukraine, strengthening its hand militarily and diplomatically as it defends against Russian aggression. At home, I am determined to ensure that democracy continues delivering for our people—making lives better in meaningful, concrete ways.

To all the people around the world striving toward a better future—a future rooted in democracy and fundamental freedoms, hope and light, decency and dignity—the United States stands with you. From the Ukrainian soldiers fighting for their nation's very existence, to the brave women of Iran organizing to secure their human rights and fundamental freedoms, the people of Burma demanding democracy in the face of brutal violence, and the Cuban citizens standing up against oppression—the courage and commitment that helped bring down the Berlin Wall remains alive and powerful around the world today. History shows us that it is from the darkest moments that the greatest progress follows. That is true thanks to brave people who are bending the arc of history toward a freer and more just world.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, do hereby proclaim November 9, 2022, as World Freedom Day. I call upon the people of the United States of America to recall the hope symbolized by the fall of the Berlin Wall and reaffirm our dedication to freedom and democracy.

IN WITNESS WHEREOF, I have hereunto set my hand this eighth day of November, in the year of our Lord two thousand twenty-two, and of the Independence of the United States of America the two hundred and forty-seventh.

R. Beden. Ja

[FR Doc. 2022–24844 Filed 11–10–22; 8:45 am] Billing code 3395–F3–P

Rules and Regulations

Federal Register

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

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Doc. No. AMS-NOP-21-0060]

RIN 0581-AE11

Amendments to the National List of Allowed and Prohibited Substances per October 2020 and April 2021 NOSB Recommendations (Handling, Crops)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule amends the National List of Allowed and Prohibited Substances (National List) section of the United States Department of Agriculture's (USDA) organic regulations to implement recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB). This rule allows low-acyl gellan gum, a food additive used as a thickener, gelling agent, and stabilizer, as an ingredient in processed organic products. This rule also allows paperbased crop planting aids for organic crop production. Finally, this rule replaces the term "wood resin" on the National List with the term "wood rosin" to reflect the popular spelling of the substance.

DATES: This rule is effective on December 14, 2022.

FOR FURTHER INFORMATION CONTACT:

Jared Clark, Standards Division, National Organic Program. Telephone: (202) 720–3252. Email: *Jared.Clark@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

On December 21, 2000, the Secretary established the Agricultural Marketing Service's (AMS) National Organic Program (NOP) and the USDA organic regulations (65 FR 80547, December 21, 2000). Within the USDA organic regulations (7 CFR part 205) is the National List of Allowed and Prohibited Substances (or "National List"). The National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic crop and livestock production. It also identifies the nonorganic substances that may be used in or on processed organic products.

AMS is finalizing three amendments to the National List in accordance with the procedures detailed in the Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6501–6524). OFPA establishes what may be included on the National List and the procedures that the USDA must follow to amend the National List (7 U.S.C. 6517). OFPA also describes the NOSB's responsibilities in proposing amendments to the National List, including the criteria for evaluating amendments to the National List (7 U.S.C. 6518).

According to OFPA's requirements, substances on the National List must be: (1) reviewed every five years by the NOSB, a 15-member Federal advisory committee; and (2) renewed by the Secretary to remain on the National List (7 U.S.C. 6517(e)). This action of NOSB review and USDA renewal is commonly referred to as the "sunset review" or "sunset process." AMS published information about this process in the Federal Register on September 16, 2013 (78 FR 56811). The sunset date (i.e., the date by which the Secretary must renew a substance for the listing to remain valid on the National List) for each substance is included in the NOP Program Handbook (document NOP 5611). The sunset date for the two substances added to the National List by this rule will be five years after the effective date noted in the DATES section above. The sunset date for wood rosin is unchanged by this rule and remains March 15, 2027 (86 FR 41699, August 3, 2021).

Overview of Amendments

This rule adds low-acyl gellan gum and paper-based crop planting aids to the National List. This rule also adds a definition for "paper-based crop planting aids" to 7 CFR 205.2. Once this rule becomes effective, organic crop producers and organic handlers will be allowed to use these substances in

organic crop production and handling, as applicable. The permitted use of each substance is discussed in detail below. This rule also replaces the term "wood resin" at 7 CFR 205.605(a) with the term "wood rosin" to reflect the popular spelling of the substance. Additional background on the petitions and on the NOSB's review of these substances may be found in the proposed rule (87 FR 5424, February 1, 2022).

During a 60-day comment period that closed on April 4, 2022, AMS received 45 comments on the proposed rule. See below for a discussion of the comments received and AMS's responses to comments. Comments can be viewed at Regulations.gov. Use the search area on the homepage at https://www.regulations.gov to enter a keyword, title, or docket ID (the docket ID for this rule is AMS-NOP-21-0060).

A. Low-Acyl Gellan Gum (§ 205.605(b))

Section 205.605(b) Nonagricultural synthetic substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

Overview

This rule amends the National List to add low-acyl gellan gum to 7 CFR 205.605(b) as a nonagricultural, synthetic substance allowed for use in organic handling as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." Low-acyl gellan gum is a polysaccharide (type of carbohydrate) produced through fermentation (from the microorganism Sphingomonas elodea). It is manufactured from highacyl gellan gum, a substance allowed in organic production, which is isolated from microbial fermentation. Low-acyl gellan gum is used in a wide variety of food products that require gelling, texturizing, stabilizing, suspending, film-forming, and structuring such as ready-to-eat dessert gels, icings, and beverages.

AMS is finalizing this amendment to the National List, as recommended by the NOSB after its October 2020 public meeting, 1 to provide organic handlers

¹ National Organic Standards Board, formal recommendation, low-acyl gellan gum, October 30, 2020, https://www.ams.usda.gov/sites/default/files/ media/HSLowAcylGellanGumRec_webpost.pdf.

an ingredient for thickening, gelling, and stabilizing. Synthetic low-acyl gellan gum is made from natural high-acyl gellan gum, which is already allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" (§ 205.605(a)).

Low-acyl gellan gum holds unique qualities not found in other thickener substances on the National List (e.g., high-acyl gellan gum, carrageenan). While high-acyl gellan gum produces gels that are soft, elastic, and non-brittle, low-acyl gellan gum can be used to create a firmer, harder, and non-elastic gel. Food producers can vary the ratios of both high- and low-acyl gellan gums to produce different textures. Low-acyl gellan gum can also be used to increase viscosity of beverages or be used to suspend matter in beverages, such as those containing fruit pulp or jelly pieces. Additionally, low-acyl gellan gums can be clarified to create a gel with better clarity than other gumsimportant for certain confectionary applications such as icings and fillings. Gellan gums can better withstand higher temperatures while maintaining their gel form than other gelling agents, such as gelatin, can. Additionally, low-acyl gellan gum can be used in standard processing without additional steps (e.g., compared to pectin, which requires special handling in gelled confections). Finally, low-acyl gellan gum provides a vegetarian alternative to gelatin in hard and soft capsules used for products such as dietary supplements.

NOSB Review and Recommendation

Following review of an August 2019 petition,² the NOSB recommended that low-acyl gellan gum be added to the National List.¹ The NOSB's evaluation of low-acyl gellan gum considered comments from the public, a previously commissioned third-party technical report on gums,⁴ and the petition itself. The NOSB discussed this petition in

subcommittee calls and at its public meeting in October 2020.⁵

After their evaluation, the NOSB concluded that adding low-acyl gellan gum to the National List is consistent with the evaluation criteria in OFPA (7 U.S.C. 6518(m)). The NOSB concluded that low-acyl gellan gum has minimal adverse effects on the environment and human health. Additionally, the NOSB acknowledged the distinct properties of low-acyl gellan gum and noted that it can be used to manufacture hard, nonelastic, brittle gels (unlike high-acyl gellan gum). This property allows it to be used in the production of capsules used for dietary supplements. Notably, its allowance by this rule will give organic handlers an alternative to gelatin to produce vegetarian and vegan products—an important attribute for a segment of consumers.

The NOSB recommended that lowacyl gellan gum be classified as "synthetic". As defined by OFPA and the USDA organic regulations, a synthetic substance is produced by a chemical process, or by a process that chemically changes a natural substance (7 U.S.C. 6502(22) and 7 CFR 205.2). As the manufacturing process for low-acyl gellan gum includes the deacetylation of high-acyl gellan gum (reducing the number of acetyl groups 6 by adding potassium, magnesium, calcium, and/or sodium salts), which is considered a chemical change, the NOSB determined this is a synthetic substance.

Comments Received and AMS Responses

AMS received 16 comments in response to the proposed listing of low-acyl gellan gum from a diverse audience, including: certified operations, certifying agents, trade groups, substance manufacturers, and the public. The subjects of these comments and responses from AMS are covered in this section. AMS is finalizing the addition of low-acyl gellan gum as drafted in the proposed rule.

The majority of commenters were in favor of adding low-acyl gellan gum to the National List and agreed with the NOSB's recommendation. Commenters supported the addition based on the absence of evidence that low-acyl gellan gum is harmful to human health or the

environment and based on the FDA allowance of low-acyl gellan gum as a food additive. Additionally, commenters stated this substance is necessary and would support market development of organic products, due to the lack of wholly natural thickeners with similar properties.

A few comments were opposed to the addition of the substance to the National List. Two commenters expressed concern that a manufacturer of low-acyl gellan gum petitioned for the addition to the National List and stood to benefit from inclusion of the substance.

Another commenter was opposed due to the processed nature of the substance.

AMS notes that the National List is an optional list of generic substances that an operation may use in their products. Petitions to amend the National List may be submitted by any person, and substances on the National List may be produced by any manufacturer. Furthermore, OFPA expressly permits nonorganic ingredients in organic handling, including synthetic ingredients included on the National List for use in organic processed products. These individual synthetic ingredients must meet the criteria in OFPA (e.g., not harmful to human health and the environment), as evaluated by the NOSB and AMS, and undergo rulemaking to add them to the National List. The NOSB and AMS evaluated low-acyl gellan gum and determined that it met the statutory requirements for addition to the National List.

Some commenters misperceived the proposed rule as allowing low-acyl gellan gum for use by farmers in organic crop production. AMS does not respond to these comments, as the rule does not allow low-acyl gellan gum in crop production. The rule allows use of low-acyl gellan gum in organic handling (i.e., processing). One of these commenters expressed concern with negative health effects associated with overconsumption of gellan gum and mentioned an unnamed animal study.

After review of the comment, AMS concluded that allowance of low-acyl gellan gum is not likely to be harmful to human health. First, gellan gum is listed by the Food & Drug Administration (FDA) as a safe food additive permitted for direct addition to food for human consumption at 21 CFR 172.665. The FDA requires prescribed conditions for its safe use, including following good manufacturing practices (21 CFR 172.665(e)). Additionally, the rule only allows limited use of low-acyl gellan gum, as allowed synthetic substances cannot be used at levels greater than 5 percent (by weight or

² Petition for Evaluation of Low Acyl Gellan Gum for Inclusion on the National List of Substances Allowed in Organic Production and Handling (7 CFR 205.605(b), CP Kelco U.S., Inc., National List Petition, August 8, 2019, https://www.ams.usda.gov/sites/default/files/media/PetitionLowAcylGellanGum08082019.pdf.

³ Response To Request For Information Low Acyl Gellan Gum, CP Kelco U.S., Inc., National List Petition Update, March 6, 2020, https:// www.ams.usda.gov/sites/default/files/media/ PetitionAddendum_LAGellanGum_ ResponsetoNOSB_03062020.pdf.

⁴ National Organic Program, Gums, Nexight Group, technical report, January 30, 2018, https:// www.ams.usda.gov/sites/default/files/media/ GumsTRFinal20180130.pdf.

⁵ National Organic Standards Board (NOSB) Meeting—Virtual, National Organic Standards Board, October 28, 2020, https:// www.ams.usda.gov/event/national-organicstandards-board-nosb-meeting-cedar-rapids-iowa.

 $^{^6}$ The number of acetyl groups determines the firmness of the gel. An acetyl group is a molecule made up of a methyl group single-bonded to a carbonyl (CH $_3$ CO).

fluid volume, excluding water and salt) in products labeled "organic" (§ 205.301(b)). As a food additive, lowacyl gellan gum will be used to thicken, gel, and stabilize processed organic products.

AMS Review

As described in the BACKGROUND section, OFPA establishes what may be included on the National List and the procedures that AMS must follow to amend the National List. As directed by OFPA, AMS must show that a substance: is not harmful to human health or the environment; is necessary for handling because of the unavailability of wholly natural substitute products; and is consistent with organic handling. OFPA also describes the NOSB's responsibilities in recommending amendments to the National List, including evaluation criteria.

First, AMS agrees with the classification of low-acyl gellan gum as a "synthetic" substance, as the process of removing acetyl groups by deacetylation fits the definition of "synthetic" at 7 CFR 205.2 and 7 U.S.C. 6502 and as described in AMS published guidance on the classification of materials.

AMS also concludes that the addition of low-acyl gellan gum to the National List is consistent with the requirements of OFPA (7 U.S.C. 6517(c)(1)(A)). While NOSB determined that low-acvl gellan gum had minimal adverse effects on the environment and human health, AMS determined there is no impact. First, low-acyl gellan gum is not harmful to human health or the environment, as gellan gum is listed by the Food & Drug Administration (FDA) as a food additive permitted for direct addition to food for human consumption at 21 CFR 172.665. Additionally, gellan gum is allowed as an inert ingredient in minimum risk pesticides (i.e., pesticide products exempt from the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)) by the U.S. Environmental Protection Agency (EPA) at 40 CFR 152.25(f)(2)(iv)). Second, lowacyl gellan gum is necessary because of the absence of wholly natural substitute products, as evidenced by public comment submitted to the NOSB and as reported in the 2018 technical report. Finally, the use of low-acyl gellan gum is consistent with organic handling. This amendment follows the NOSB recommendation according to the

procedures established in OFPA (7 U.S.C. 6517(d)).

B. Paper-Based Crop Planting Aids (§ 205.601(o)(2))

Section 205.601(o) Synthetic production aids allowed for use in organic crop production

Overview

This rule amends the National List to add paper-based crop planting aids to 7 CFR 205.601 as a synthetic substance allowed for use in organic crop production. This rule also adds a definition for paper-based crop planting aids to the USDA organic regulations (§ 205.2, Terms defined). Together, these amendments allow use of paper-based crop planting aids, including those that are placed in or on the soil and later incorporated into the soil.

AMS is finalizing this amendment to the National List, as recommended by the NOSB after its April 2021 meeting, 8 to provide certified operations an additional tool for planting or transplanting crops. Paper-based crop planting aids (e.g., individual pots, chain pots, seed tape, collars) provide an alternative to the slower and more costly method of planting or transplanting individual crops by hand.

NOSB Review and Recommendation

Following review of a petition submitted in August 2018, 9 10 the NOSB recommended adding paper-based crop planting aids to the National List and recommended a regulatory definition of these products. In their evaluation of paper-based crop planting aids, the NOSB considered comments from the public, a commissioned technical report on paper-pots and containers, 11 previously commissioned technical reports on newspaper, 12 13 and the

petition itself. The NOSB discussed the petition to amend the National List in subcommittee calls and at its public meetings in October 2018, ¹⁴ April and October 2019, ¹⁵ April and October 2020, ¹⁷ and April 2021, ¹⁸

After their evaluation, the NOSB concluded that adding paper-based crop planting aids to the National List is consistent with evaluation criteria in OFPA (7 U.S.C. 6518(m)). The NOSB found that the use of paper-based crop planting aids is compatible with organic crop production and provides benefits compared to planting or transplanting crops by hand. The NOSB recommended classifying paper-based crop planting aids as "synthetic" due to the manufacturing process. As defined by OFPA and the USDA organic regulations, a synthetic substance is produced by a chemical process or by a process that chemically changes a natural substance (7 U.S.C. 6502(22) and 7 CFR 205.2). Manufacturing paper includes breaking down wood chips into paper pulp through either acidic or alkaline chemical reactions, so it meets this definition of "synthetic". Additionally, paper is classified as synthetic for other uses on the National List (§ 205.601).

Comments Received and AMS Responses

AMS received 38 comments in response to the proposed listing of paper-based crop planting aids. Most comments supported the addition of paper-based crop planting aids for organic crop production to the National List. Many comments were from

⁷ National Organic Program, NOP 5033 Classification of Materials, guidance, December 2, 2016, https://www.ams.usda.gov/sites/default/files/ media/NOP-5033.pdf.

⁸ National Organic Standards Board, Formal Recommendation, paper-based crop planting aids, April 30, 2021, https://www.ams.usda.gov/sites/ default/files/media/CSPaperBasedCropPlanting Aids_FinalRec.pdf.

⁹Petition for hemp paper or other paper, without glossy or colored inks, as a plant pot or growing container, Small Farm Works, National List Petition, August 7, 2018, https:// www.ams.usda.gov/sites/default/files/media/ PaperPotorContainerPetition080718.pdf.

¹⁰ Petition Addendum Regarding Paper Pot Adhesives, Small Farm Works, National List Petition, October 2, 2018, https:// www.ams.usda.gov/sites/default/files/media/ PetitionAdendumPaperPots10022018.pdf.

¹¹ National Organic Program, Paper Pots and Containers, Nexight Group and Organic Materials Review Institute, technical report, July 26, 2019, https://www.ams.usda.gov/sites/default/files/ media/PaperTRFinal7262019.pdf.

¹² National Organic Program, Newspaper or Other Recycled Paper, ICF Consulting, technical report, January 27, 2006, https://www.ams.usda.gov/sites/ default/files/media/ Newspaper%20TR%202006.pdf.

¹³ National Organic Program, Newspaper or Other Recycled Paper, Organic Materials Review Institute, technical report, January 11, 2017, https:// www.ams.usda.gov/sites/default/files/media/ Newspaper%20TR%20Final%20 01%2011%2017.pdf.

¹⁴ National Organic Standards Board (NOSB) Meeting—St. Paul, MN, National Organic Standards Board, October 24, 2018, https:// www.ams.usda.gov/event/national-organicstandards-board-nosb-meeting-st-paul-mn.

¹⁵ National Organic Standards Board (NOSB) Meeting—Seattle, WA, National Organic Standards Board, April 24, 2019, https://www.ams.usda.gov/ event/national-organic-standards-board-nosbmeeting-seattle-wa.

¹⁶ National Organic Standards Board (NOSB) Meeting—Pittsburgh, PA, National Organic Standards Board, October 23, 2019, https:// www.ams.usda.gov/event/national-organicstandards-board-nosb-meeting-pittsburgh-pa.

¹⁷ National Organic Standards Board (NOSB) Meeting—Virtual, National Organic Standards Board, April 29, 2020, https://www.ams.usda.gov/ event/national-organic-standards-board-nosbmeeting-crystal-city-va.

¹⁸ National Organic Standards Board (NOSB) Meeting—Virtual, National Organic Standards Board, April 28, 2021, https://www.ams.usda.gov/ event/national-organic-standards-board-nosbmeeting-crystal-city-va-0.

certified organic operations. Commenters supported the use of paperbased crop planting aids on account of improved efficiency in transplanting crops. Commenters indicated that these products would allow smaller operations to exponentially increase planting efficiency and save money on labor while retaining organic certification. Many commenters also cited the environmental benefit of reduced plastic waste, as paper-based crop planting aids could replace plastic seedling trays and pots.

The subjects of public comments and responses from AMS are described below. The rule makes minor modifications to the definition of ''paper-based crop planting aids'' (§ 205.2) and to introductory language in the National List (§ 205.601) to clarify the intent and meaning of the amendments. These comments and changes are discussed below.

Several commenters, including certifying agents, material review organizations, and trade groups, recommended removal of the last sentence in the proposed definition for "paper-based crop planting aids": "Added nutrients must comply with §§ 205.105, 205.203, and 205.206". The commenters indicated that the statement was unclear, inaccurate, and/ or unnecessary. They indicated that certified organic crop operations are already required to comply with overarching requirements in the USDA organic regulations related to allowed and prohibited substances, methods, and ingredients (§ 205.105) as well as requirements related to soil fertility and crop nutrient management (§ 205.203). They argued that references to these sections of the USDA organic regulations would therefore be redundant. Commenters also indicated that the reference to crop pest, weed, and disease management practice standards (§ 205.206) would be inappropriate because that section of the regulations does not relate to "nutrients".

AMS agrees with the commenters that the references to §§ 205.105, 205.203 and 205.206 within the definition of "paper-based crop planting aid" are unnecessary. Sections 205.105 and 205.203 apply to all certified organic crop operations, and reference to the crop pest, weed, and disease management practice standards (§ 205.206) is not relevant or necessary to the definition. AMS has modified the definition of "paper-based crop planting aid" in this rule to remove these references from the definition.

One commenter suggested an update to the regulatory text found in the

introduction to the crop substances section of the National List (§ 205.601). The current language here exempts certain categories of synthetic substances on the National List from certain provisions of the USDA organic regulations, specifically, the requirements to first use crop pest, weed, and disease preventive practices and nonsynthetic substances prior to the use of synthetic substances on the National List. For example, synthetic compost feedstocks, plant and soil amendments, plant growth regulators, and floating agents used in postharvest handling, are currently allowed in organic crop production without regard to these preventive practices. The commenter suggested that AMS update the language to clarify that crop production aids, including paper-based crop planting aids, may also be used without regard to those preventive practices. A commenter also suggested that AMS should clarify that fatty alcohols containing allowed synthetic inert ingredients (§ 205.601(m)) are similarly exempt.

AMS agrees that the introductory text at § 205.601 should be updated to include crop production aids as exempt from the provisions set forth in § 205.206(a) through (d). Crop production aids specifically included at § 205.601(o) may be used by producers without first considering other alternative practices or nonsynthetic substances for preventing crop pests, weeds, and diseases. For example, paper-based chain pots are used to transplant seedlings into a field. It would be confusing and impractical for the USDA organic regulations to first require the use of transplanting by hand, or first require the use of nonsynthetic substances, prior to allowing use of paper-based chain pots. The rule updates the introductory text for this section of the National List (the specific modifications to the regulatory text can be found at the bottom of this document). AMS is not updating the text to address the comment related to fatty alcohols containing inert ingredients, as the substance was not included or discussed as part of the proposed rule. AMS may consider additional changes to the introductory text for this section of the National List in a future proposed rule.

In the proposed rule, AMS specifically requested public comment on the interpretation of the wording in the proposed definition that references the qualifications of people tasked with determining the biobased content of these products. As discussed in the proposed rule, AMS interprets

"qualified personnel" to be a third-party

(i.e., certifying agent or material review organization, see NOP Program Handbook NOP 3012 "Material Review—Interim Instruction") 19 capable and qualified to make limited biobased determinations. AMS stated that if the biobased nature of the ingredients were clear (e.g., a product composed entirely of paper and coconut coir), then the review of the product could be performed by qualified personnel without a laboratory test (ASTM D6866). A discussion of comments received on this topic follows. The rule makes no changes related to "qualified personnel".

Several commenters, including certifying agents, material review organizations, and trade groups, agreed that "qualified personnel" would include certifying agents and material review organizations. Of these commenters, a certifying agent and material review organization expressed confidence in their ability to evaluate the biobased content of some paperbased crop planting aids outside of an ASTM D6866 laboratory result. Several paper-based crop planting aid manufacturers also submitted comments. These manufacturers indicated that they currently produce products that meet the composition requirements. Some stated that they plan to work with a material review organization to verify compliance with the USDA organic regulations following publication of this rule.

One commenter, a certifying agent, expressed concern that the definition lacked clarification on what constitutes "qualified personnel". This commenter also expressed overall concerns with the composition requirements. The commenter stated that they deviate significantly from current industry standards and practices, as no products currently available cite third-party standards or provide detailed information on the percentage of biobased or cellulose content. This commenter indicated that the detailed requirements regarding cellulose and biobased content would require both product manufacturers and certifying agents to perform multiple calculations, demanding more time and expense of certifying agents without affording significant tangible benefits to organic integrity. This commenter requested that AMS clearly set out minimum qualifications to meet the definition of "qualified personnel" and specify methods to be used to determine

¹⁹ National Organic Program, NOP 3012 Material Review, Interim Instruction, August 30, 2016, https://www.ams.usda.gov/sites/default/files/ media/NOP%203012%20Material%20Review.pdf.

biobased content outside of an ASTM D6866 laboratory result.

AMS appreciates the public comments in response to AMS's questions set forth in the proposed rule. AMS is not making additional changes from the proposed rule in this rule regarding "qualified personnel". Formulation review of products composed of allowed substances is a common practice among certifiers and material review organizations to ensure that products are compliant with the USDA organic regulations. If the biobased nature of the ingredients is unclear, then the composition of the product should be determined by a laboratory test (ASTM D6866). AMS expects much of the paper-based crop planting aids review process to fit into current product formulation evaluation processes and via the ASTM D6866 standard. AMS encourages certifying agents and material review organizations and other qualified third parties to consult guidance previously set forth by AMS, which encourages certifying agents to consult with each other regarding material review.19

One commenter expressed concern with specific reference to only synthetic substances allowed as plant or soil amendments—on the National List at § 205.601(j))—in the definition of "paper-based crop planting aids." This commenter suggested that it is not necessary to refer to these substances because material reviewers should review added ingredients against the relevant subsection of the National List.

AMS disagrees with the suggestion to remove reference to synthetic substances allowed as plant and soil amendments (§ 205.601(j)) from the definition, thereby allowing the inclusion of any synthetic substances on the National List for organic crop production. The rule aligns with the NOSB's recommendation on this topic. During the development of their recommendation, the NOSB considered whether the non-cellulose content of these products could include synthetic pest and disease control substances from the National List. The NOSB discarded this option, stating, for example, that pesticides embedded in these products could have adverse impacts on biodiversity.

AMS agrees that organic producers may only use synthetic substances on the National List for crop pest, weed, and disease control when other practices (see § 205.206) are insufficient to prevent or control crop pests, weeds, and diseases. The rule does not allow synthetic pesticides in paper-based crop planting aids, as inclusion of these substances would likely lead to

prophylactic use of synthetic substance(s). The use of synthetic substances in this manner is not permitted by the USDA organic regulations (§ 205.206(e)).

In accordance with the NOSB recommendation, the rule only permits the addition of the following synthetic substances in paper-based crop planting aids: substances on the National List in § 205.601(j) as plant and soil amendments; and ingredients used in strengthening fibers, adhesives, or resins.

One commenter opposed the allowance of synthetic strengthening fibers, adhesives, and resins in the definition of paper-based crop planting aids. The commenter indicated that the synthetic allowances are unnecessary and that the proposed composition requirements would not drive manufacturers to develop products with fewer synthetic ingredients. They indicated that a pot, made from only paper, could be dipped in natural rubber and yield the same labor-saving advantages as the proposed paper-based crop planting aids.

AMS disagrees with prohibiting synthetic strengthening fibers, adhesives, and resins. First, as outlined in the OVERVIEW section, paper-based crop planting aids include not only individual pots but also products such as chain pots, seed tape, and collars. Second, paper-based crop planting aids require strengthening additives to increase "wet strength" so that they will not breakdown prior to transplanting. These additional synthetic substances allow paper-based crop planting aids to hold their structure and resist breakdown in the presence of water, soil media, and plant roots.11

One commenter urged AMS to update the reference to the ASTM standard ASTM D6866 in future rulemaking, as incorporated into the USDA organic regulations by reference (see § 205.3, *Incorporation by reference*). They also urged AMS to include regular review of the incorporated references listed in § 205.3, such as when National List substances go through the sunset review process.

AMS recognizes that the standards incorporated into the USDA organic regulations by reference are subject to change over time, and AMS understands a newer version of the ASTM D6866 standard has been adopted by ASTM (currently ASTM D6866–22, adopted in 2022 compared to ASTM D6866–12 referenced in the USDA organic regulations and adopted in 2012). AMS intends to update the reference to ASTM D6866–12 and to other references (§ 205.3) in future rulemaking.

AMS Review

AMS concludes that adding paperbased crop planting aids to the National List is consistent with the requirements of OFPA (7 U.S.C. 6517(c)(1)(A)), and this amendment adopts the NOSB recommendation according to OFPA procedures (7 U.S.C. 6517(d)). Paperbased crop planting aids appear to be necessary due to the lack of wholly nonsynthetic (natural) substitute products. Additionally, paper-based crop planting aids are expected to readily break down in the soil and do not appear to be harmful to human health or the environment when used for crop planting or transplanting purposes. This conclusion is supported by the presence of paper on EPA's list of "inert ingredients permitted in minimum risk pesticide products" at 40 CFR 152.25(f)(2)(iv). Furthermore, the addition of paper for these uses is consistent with the other allowed uses of paper under the USDA organic regulations, namely, as a mulch (7 CFR 205.601(b)(2)(i)) and compost feedstock (§ 205.601(c)). AMS also notes and agrees with comments that allowance of paper-based crop planting aids could reduce use of plastic, thereby providing an environmental benefit.

Finally, AMS agrees with the NOSB's classification of paper-based crop planting aids as a "synthetic" substance, as the acid-base reactions included in the kraft process of manufacturing paper, as well as the inclusion of additional synthetic substances to improve performance, fit the definition of "synthetic" as described in the USDA organic regulations (7 CFR 205.2) and AMS published guidance on the classification of materials.⁷

C. Wood Rosin (sic. Resin; § 205.605(a))

Section 205.605(a) Nonagricultural nonsynthetic substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

Overview

This rule amends the National List to update the spelling of "wood resin" to "wood rosin" in the definition of "waxes" at 7 CFR 205.605(a).

NOSB Review and Recommendation

Following the 2022 sunset review for wood resin, the NOSB recommended a correction to the spelling of "wood resin" (to "wood rosin") on the National List. "Wood resin" is currently included on the National List as an allowed nonorganic substance in or on processed products labeled as "organic" or "made with organic (specified ingredients or

food group(s))." ²⁰ The NOSB stated in this recommendation that "wood rosin" is the more accurate and current spelling and that AMS should replace the word "resin" with "rosin". The NOSB discussed the recommendation for this technical correction in subcommittee calls and at its public meeting in October 2020.⁵

AMS Review and Comments Received

AMS concludes that "resin" can also refer to "rosin"—as noted by AMS in a 1997 proposed rule (62 FR 65850, December 16, 1997)—but AMS agrees "rosin" is the preferred term because it is more specific to the wood product and aligns more closely with the use of the term in the market. Additionally, the spelling "rosin" more closely aligns with FDA (21 CFR 178.3870, Rosins and rosin derivatives) and World Health Organization definitions for food-grade rosin.²¹ AMS does not expect this spelling modification to have any impact on organic handlers.

ÂMS received six comments in response to the proposed technical correction of "wood resin" to "wood rosin". All public submissions supported the correction. The rule replaces the term "Wood resin" with "Wood rosin" at 7 CFR 205.605(a).

Related Documents

AMS published notices in the **Federal Register** announcing the Fall 2020 NOSB Meeting (85 FR 54343, September 1, 2020) and announcing the Spring 2021 NOSB meeting (86 FR 10161, February 18, 2021). These notices invited public comments on the NOSB recommendations addressed in this rule. The AMS proposed rule, which preceded this rule, was published on February 1, 2022 (87 FR 5424).

Statutory and Regulatory Authority

OFPA authorizes the Secretary to make amendments to the National List based on recommendations developed by the NOSB. OFPA authorizes the NOSB to develop recommendations for submission to the Secretary to amend the National List and to establish a process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List (7 U.S.C. 6518(k) and (n)). Section 205.607 of the

USDA organic regulations permits any person to petition to add or remove a substance from the National List and directs petitioners to obtain the petition procedures from USDA (7 CFR 205.607). The current petition procedures published in the **Federal Register** (81 FR 12680, March 10, 2016) for amending the National List can be accessed through the NOP Program Handbook on the AMS website at https://www.ams.usda.gov/rules-regulations/organic/handbook.

Executive Orders 12866 and 13563 and the Regulatory Flexibility Act

This rule does not meet the criteria of a significant regulatory action under Executive Order 12866 as supplemented by Executive Order 13563. Therefore, the Office of Management and Budget (OMB) has not reviewed this rule under those orders.

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

The Small Business Administration (SBA) sets size criteria for each industry described in the North American Industry Classification System (NAICS) to delineate which operations qualify as small businesses.²² The SBA classifies small agricultural producers that engage in crop and animal production as those with average annual receipts of less than \$2 million (13 CFR 121.201). Handlers are involved in a broad spectrum of food production activities and fall into various categories in the NAICS Food Manufacturing sector. The small business thresholds for food manufacturing operations are based on the number of employees and range from 500 to 1,250 employees, depending on the specific type of manufacturing. Certifying agents fall under the NAICS subsector "all other professional, scientific and technical services." For this category, the small business

threshold is average annual receipts of less than \$17 million.

Producers. AMS has considered the economic impact of this rulemaking on small agricultural entities. Data collected by the USDA National Agricultural Statistics Service (NASS) and the NOP indicate most of the certified organic production operations in the United States would be considered small entities. According to the 2019 Certified Organic Survey. 16,524 organic farms in the United States reported total sales of organic products and total farmgate sales more than \$9.9 billion.23 Based on that data, organic sales average \$601,000 per farm. Assuming a normal distribution of producers, we expect that most of these producers would fall under the \$2 million sales threshold to qualify as a small business.

Handlers. According to the NOP's Organic Integrity Database (OID), there are 10,896 U.S.-based organic handlers that are certified under the USDA organic regulations.²⁴ The Organic Trade Association's 2021 Organic Industry Survey has information about employment trends among organic manufacturers.²⁵ The reported data are stratified into three groups by the number of employees per company: fewer than 5; 5 to 49; and 50 plus. These data are representative of the organic manufacturing sector, and the lower bound (50) of the range for the larger manufacturers is notably smaller than the SBA's small business thresholds (500 to 1,250). Therefore, AMS expects that most organic handlers would qualify as small businesses.

Certifying agents. The SBA defines "all other professional, scientific, and technical services," which include certifying agents, as those having annual receipts of less than \$17 million (13 CFR 121.201). There are currently 75 USDAaccredited certifying agents,24 based on a query of the OID database, who provide organic certification services to producers and handlers. While many certifying agents are small entities that would be affected by this rule, we do not expect that these certifying agents would incur significant costs as a result of this action, as certifying agents already must comply with the current

²⁰ National Organic Standards Board, formal recommendation, handling 2022 sunset reviews, October 30, 2020, https://www.ams.usda.gov/sites/default/files/media/HS2022SunsetRecs_webpost.pdf.

²¹ Joint FAO/WHO Expert Committee on Food Additives. (1975). Toxicological Evaluation of Some Food Colours, Enzymes, Flavour Enhancers, Thickening Agents, and Certain Food Additives (No. 6). World Health Organization.

²² U.S. Small Business Administration (SBA), Table of Small Business Size Standards Matched to North American Industry Classification System Codes, May 2, 2022, https://www.sba.gov/ document/support-table-size-standards.

²³ USDA, National Agricultural Statistics Service (NASS), 2017 Census of Agriculture, Volume 1, Chapter 1 US, https://www.nass.usda.gov/ Publications/AgCensus/2017/Full_Report/Volume_ 1,_Chapter_1_US/.

²⁴ USDA, Agricultural Marketing Service, Organic Integrity Database, Accessed June 9, 2022, https:// organic.ams.usda.gov/Integrity/.

²⁵ Organic Trade Association (OTA), U.S. Organic Industry Survey 2021, available for purchase from https://ota.com/market-analysis/organic-industry-survey/organic-industry-survey.

regulations (e.g., maintaining certification records for organic operations).

AMS concludes that this rule will not have any significant economic impact on small entities or affect a substantial number of small entities. The effect of this rule is that additional substances will be allowed in organic handling and organic crop production (low-acyl gellan gum and paper-based crop planting aids). The allowance of these substances will provide entities, including small entities, with more options in their day-to-day operations.

Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This rule is not intended to have a retroactive effect. Accordingly, to prevent duplicative regulation, states and local jurisdictions are preempted under OFPA from creating programs of accreditation for private persons or state officials who want to become certifying agents of organic farms or handling operations. A governing state official would have to apply to the USDA to be accredited as a certifying agent, as described in OFPA (7 U.S.C. 6514(b)). States are also preempted from creating certification programs to certify organic farms or handling operations unless the state programs have been submitted to, and approved by, the Secretary as meeting the requirements of OFPA (7 U.S.C. 6503-6507).

Pursuant to OFPA (7 U.S.C. 6507(b)(2)), a state organic certification program that has been approved by the Secretary may, under certain circumstances, contain additional requirements for the production and handling of agricultural products organically produced in the state and for the certification of organic farm and handling operations located within the state. Such additional requirements must (a) further the purposes of OFPA, (b) not be inconsistent with OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

In addition, pursuant to 7 U.S.C. 6519(c)(6), this rule does not supersede or alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601–624), the Poultry Products Inspection Act (21 U.S.C. 451–471), or the Egg Products Inspection Act (21 U.S.C. 1031–1056) concerning meat, poultry, and egg products, respectively, nor any of the authorities of the

Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), nor the authority of the Administrator of the EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 et seq.).

Paperwork Reduction Act

Routine collection, reporting, and recordkeeping related to the use of substances on the National List is included in NOP's approved information collection request (OMB control number 0581–0191). No additional collection or recordkeeping requirements are imposed on the public by this rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35.

Executive Order 13175

This rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments. Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments, or proposed legislation. Additionally, other policy statements or actions that have substantial direct effects on one or more Indian Tribes, the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes also require consultation.

After reviewing this rule, the Office of Tribal Relations (OTR) has determined that tribal consultation is not required. If a tribe requests consultation in the future, AMS will work with OTR to ensure meaningful consultation is provided.

Executive Order 13132

Executive Order 13132 mandates that Federal agencies consider how their policymaking and regulatory activities impact the policymaking discretion of States and local officials and how well such efforts conform to the principles of federalism defined in said order. This Executive order only pertains to regulations with clear federalism implications.

AMS has determined that this rule conforms with the principles of federalism described in Executive Order 13132. The rule does not impose substantial direct costs or effects on States, does not alter the relationship between States and the Federal Government, and it does not alter the

distribution of powers and responsibilities among the various levels of government. States had the opportunity to comment on the proposed rule. No States provided public comment on the federalism implications of this rule. Therefore, AMS has concluded that this rule does not have federalism implications.

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).

General Notice of Public Rulemaking

This rule reflects recommendations submitted by the NOSB to the Secretary to add two substances to the National List and updates the spelling of one substance on the National List.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agricultural commodities, Agriculture, Animals, Archives and records, Fees, Imports, Labeling, Livestock, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, AMS amends 7 CFR part 205 as follows:

PART 205—NATIONAL ORGANIC PROGRAM

- 1. The authority citation for 7 CFR part 205 continues to read as follows:
 - Authority: 7 U.S.C. 6501-6524.
- 2. Amend § 205.2 by adding, in alphabetical order, a definition for "Paper-based crop planting aid" to read as follows:

§ 205.2 Terms defined.

* * * *

Paper-based crop planting aid. A material that is comprised of at least 60% cellulose-based fiber by weight, including, but not limited to, pots, seed tape, and collars that are placed in or on the soil and later incorporated into the soil, excluding biodegradable mulch film. Up to 40% of the ingredients can be nonsynthetic, other permitted synthetic ingredients in § 205.601(j), or synthetic strengthening fibers, adhesives, or resins. Contains no less than 80% biobased content as verified by a qualified third-party assessment (e.g., laboratory test using ASTM D6866 or composition review by qualified personnel).

* * * * *

■ 3. Amend § 205.601 by revising the introductory text and paragraph (o) to read as follows:

§ 205.601 Synthetic substances allowed for use in organic crop production.

In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production: *Provided*, That, use of such substances do not contribute to contamination of crops, soil, or water. Substances allowed by this section, except disinfectants and sanitizers in paragraph (a) and those substances in paragraphs (c), (j), (k), (l), and (o) of this section, may only be used when the provisions set forth in § 205.206(a) through (d) prove insufficient to prevent or control the target pest.

(o) Production aids.

(1) Microcrystalline cheesewax (CAS #'s 64742–42–3, 8009–03–08, and 8002–74–2)—for use in log grown mushroom production. Must be made without either ethylene-propylene co-polymer or synthetic colors.

(2) Paper-based crop planting aids as defined in § 205.2. Virgin or recycled paper without glossy paper or colored inks.

* * * *

- 4. Amend § 205.605 by:
- a. In paragraph (a):
- i. In the heading, removing the colon and adding a period in its place.
- \blacksquare ii. Designating the entries as paragraphs (a)(1) through (30).
- iii. Revising newly designated paragraph (a)(29).
- b. In paragraph (b):
- i. In the heading, removing the colon and adding a period in its place.
- ii. Designating the entries as paragraphs (b)(1) through (36).
- iii. Further redesignating newly designated paragraphs (b)(12)i. through iv. as paragraphs (b)(12)(i) through (iv).
- iv. Redesignating newly designated paragraphs (b)(18) through (36) as paragraphs (b)(19) through (37).
- v. Adding new paragraph (b)(18). The revision and addition read as follows:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

* * * (a) * * *

(29) Waxes—nonsynthetic (Wood rosin).

* * * * * (b) * * * (18) Low-acyl gellan gum.

Erin Morris.

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2022–24111 Filed 11–10–22; 8:45 am]

BILLING CODE P

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20, 35, 50, 51, 52, 72, 73, 110, and 150

[NRC-2022-0100]

RIN 3150-AK81

Miscellaneous Corrections

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to make miscellaneous corrections. These changes include correcting typographical errors, removing obsolete language, inserting missing language, and updating the telephone number for the NRC's Region IV office.

DATES: This final rule is effective on December 14, 2022.

ADDRESSES: Please refer to Docket ID NRC–2022–0100 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-2022-0100. Address questions about NRC dockets to Dawn Forder; telephone: 301-415-3407; email: Dawn.Forder@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, at
 301–415–4737, or by email to
 PDR.Resource@nrc.gov.
- NRC's PDR: You may examine and purchase copies of public documents, by appointment, at the PDR, Room P1

B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1–800– 397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Helen Chang, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–3228, email: Helen.Chang@nrc.gov.

SUPPLEMENTARY INFORMATION:

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II. Summary of Changes

III. Rulemaking Procedures

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V. Plain Writing

VI. National Environmental Policy Act

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VIII. Congressional Review Act

IX. Compatibility of Agreement State Regulations

I. Introduction

The NRC is amending its regulations in parts 20, 35, 50, 51, 52, 72, 73, 110, and 150 of title 10 of the *Code of Federal Regulations* (10 CFR). The NRC is making these amendments to correct typographical errors, remove obsolete language, insert missing language, and update the telephone number for the NRC's Region IV office.

II. Summary of Changes

10 CFR Parts 20 and 73

Update Telephone Number. This final rule revises appendix D to 10 CFR part 20 and appendix A to 10 CFR part 73 to update the telephone number for the NRC's Region IV office.

10 CFR Part 35

Insert Missing Language. This final rule amends § 35.13 by restoring paragraphs (b)(4)(i) through (iv), which were incorrectly removed by the 2018 final rule "Medical Event Definitions, Training and Experience, and Clarifying Amendments" (83 FR 33046; July 16, 2018).

10 CFR Part 50

Correct Typographical Error. This final rule amends the second sentence in § 50.75(e)(1)(ii)(A) to remove the text "foregoing,that" and add in its place the text "foregoing, that".

10 CFR Part 51

Remove Obsolete Language. This final rule amends the definition of "NRC staff director" in § 51.4 to update the title "Director, Office of Governmental and Public Affairs" to "Director, Office of Public Affairs" to align with the current organization, and to update the definition to an inline format.

10 CFR Part 52

Correct Typographical Error. This final rule amends footnote 2 to § 52.17 by correcting "an accidents" to read "an accident." This correction aligns footnote 2 with footnotes 4, 6, 10, and 12 to other sections within the part.

10 CFR Part 72

Correct Typographical Error. This final rule revises Certificate No. 1029 at § 72.214 by removing extra periods and aligning the text with other renewed certificates in this section.

10 CFR Part 110

Insert Missing Language. This final rule amends § 110.22 by restoring the uranium heels provision that was incorrectly removed by the 2010 final rule "Export and Import of Nuclear Equipment and Material; Updates and Clarifications" (75 FR 44072; July 28, 2010). Uranium heels were added as a provision under the general license by the final rule "Export and Import of Nuclear Equipment and Materials" (65 FR 70287; November 22, 2000). This final rule also amends the provision by adding the United Kingdom to reflect the changes that resulted from the United Kingdom's withdrawal from the European Union.

10 CFR Part 150

Insert Missing Language. This final rule amends § 150.15 by adding "or part 52 of this chapter" to paragraphs (a)(7)(iii) and (a)(8) to reference licensees under 10 CFR part 52.

Insert Missing Language. This final rule amends § 150.15 by restoring paragraph (a)(9), which was incorrectly removed by the 2014 final rule "Safeguards Information-Modified Handling Categorization; Change for Materials Facilities" (79 FR 58664; September 30, 2014).

III. Rulemaking Procedures

Under section 553(b) of the Administrative Procedure Act (5 U.S.C. 553(b)), an agency may waive publication in the **Federal Register** of a notice of proposed rulemaking and opportunity for comment requirements if it finds, for good cause, that it is impracticable, unnecessary, or contrary to the public interest. As authorized by 5 U.S.C. 553(b)(3)(B), the NRC finds good cause to waive notice and opportunity for comment on these amendments, because notice and

opportunity for comment is unnecessary. The amendments will have no substantive impact and are of a minor and administrative nature dealing with corrections to certain CFR sections or are related only to management, organization, procedure, and practice. Specifically, the revisions correct typographical errors, remove obsolete language, insert missing language, and update the telephone number for the NRC's Region IV office. The Commission is exercising its authority under 5 U.S.C. 553(b) to publish these amendments as a final rule. The amendments are effective December 14, 2022. These amendments do not require action by any person or entity regulated by the NRC and do not change the substantive responsibilities of any person or entity regulated by the

IV. Backfitting and Issue Finality

The NRC has determined that the corrections in this final rule would not constitute backfitting as defined in § 50.109, "Backfitting," and as described in NRC Management Directive (MD) 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests." These corrections also would not constitute forward fitting as that term is defined and described in MD 8.4 or affect the issue finality of any approval issued under 10 CFR part 52. The amendments are non-substantive in nature, including correcting typographical errors, removing obsolete language, inserting missing language, and updating the telephone number for the NRC's Region IV office. They impose no new requirements and make no substantive changes to the regulations. The corrections do not involve any provisions that would impose backfits as defined in 10 CFR chapter I, or that would be inconsistent with the issue finality provisions in 10 CFR part 52. For these reasons, the issuance of this final rule would not constitute backfitting or be inconsistent with any of the issue finality provisions in 10 CFR part 52. Therefore, the NRC has not prepared any additional documentation for this correction rulemaking addressing backfitting or issue finality.

V. 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).

VI. National Environmental Policy Act

The NRC has determined that this final rule is the type of action described in § 51.22(c)(2), which categorically excludes from environmental review rules that are corrective or of a minor, nonpolicy nature and do not substantially modify existing regulations. Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this rule.

VII. Paperwork Reduction Act

This final rule does not contain a collection of information as defined in the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995.

VIII. Congressional Review Act

This final rule is not a rule as defined in the Congressional Review Act (5 U.S.C. 801–808).

IX. Compatibility of Agreement State Regulations

Under the "Agreement State Program Policy Statement," approved by the Commission on October 2, 2017, and published in the Federal Register on October 18, 2017 (82 FR 48535), NRC program elements (including regulations) are placed into compatibility categories A, B, C, D, NRC, or adequacy category Health and Safety (H&S). Compatibility Category A program elements are those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner in order to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B program elements are those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C program elements are those program elements that do not meet the criteria of Category A or B but contain the essential objectives that an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a national basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D program elements are those program elements

that do not meet any of the criteria of Category A, B, or C and, therefore, do not need to be adopted by Agreement States for purposes of compatibility. Compatibility Category NRC program elements are those program elements that address areas of regulation that cannot be relinquished to the Agreement States under the Atomic Energy Act of 1954, as amended, or provisions of 10 CFR. These program

elements should not be adopted by the Agreement States. Compatibility Category H&S program elements are program elements that are required because of a particular health and safety role in the regulation of agreement material within the State and should be adopted in a manner that embodies the essential objectives of the NRC program. The portions of this final rule that amend 10 CFR parts 20, 35, and 150 are

a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements, and are listed in the following table. The changes to 10 CFR parts 50, 51, 52, 72, 73, and 110 categories are not subject to Agreement State jurisdiction and consequently are not required for compatibility.

COMPATIBILITY TABLE

Castion	Changa	Cubicat	Compatibility	
Section	Change	Subject	Existing	New
Part 20. Appendix D	Amend	United States Regulatory Commission Offices	D	D
Part 35. 10 CFR 35.13(b)	Amend	License amendments	D	D
10 CFR 150.15	Amend	Persons not exempt	NRC	NRC

List of Subjects

10 CFR Part 20

Byproduct material, Criminal penalties, Hazardous waste, Licensed material, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Penalties, Radiation protection, Reporting and recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 35

Biologics, Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Labeling, Medical devices, Nuclear energy, Nuclear materials, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 50

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

10 CFR Part 51

Administrative practice and procedure, Environmental impact statements, Hazardous waste, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 52

Administrative practice and procedure, Antitrust, Combined license, Early site permit, Emergency planning, Fees, Incorporation by reference, Inspection, Issue finality, Limited work authorization, Manufacturing license, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Penalties, Reporting and recordkeeping requirements, Standard design, Standard design certification.

10 CFR Part 72

Administrative practice and procedure, Hazardous waste, Indians, Intergovernmental relations, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

10 CFR Part 73

Criminal penalties, Exports, Hazardous materials transportation, Imports, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 110

Administrative practice and procedure, Classified information, Criminal penalties, Exports, Imports, Intergovernmental relations, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements, Scientific equipment.

10 CFR Part 150

Criminal penalties, Hazardous materials transportation, Intergovernmental relations, Nuclear energy, Nuclear materials, Penalties, Reporting and recordkeeping requirements, Security measures, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 20, 35, 50, 51, 52, 72, 73, 110, and 150:

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

■ 1. The authority citation for part 20 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 53, 63, 65, 81, 103, 104, 161, 170H, 182, 186, 223, 234, 274, 1701 (42 U.S.C. 2014, 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2210h, 2232, 2236, 2273, 2282, 2021, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); Low-Level Radioactive Waste Policy Amendments Act of 1985, sec. 2 (42 U.S.C. 2021b); 44 U.S.C. 3504 note.

■ 2. In appendix D to part 20, revise the fifth entry in the table to read as follows:

Appendix D to Part 20—United States Nuclear Regulatory Commission Regional Offices

			Address	Telephone (24 hour)	Email	
*	*	*	*	*	* *	
orado, Hawaii, Id sissippi, Montana, I North Dakota, Okl Texas, Utah, Wash	rizona, Arkansas, Califo aho, Kansas, Louisia Nebraska, Nevada, Nev ahoma, Oregon, South hington, Wyoming, and essions in the Pacific	na, Mis- v Mexico, v Dakota,	US NRC, Region IV, 1600 E Lamar Blvd., Arling- ton, TX 76011–4511.	(817) 200–1100, (800) 952–9677, TDD: (301) 415–5575.	RidsRgn4MailCenter@ nrc.gov.	

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

■ 3. The authority citation for part 35 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 81, 161, 181, 182, 183, 223, 234, 274 (42 U.S.C. 2111, 2201, 2231, 2232, 2233, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 206 (42 U.S.C. 5841, 5846); 44 U.S.C. 3504 note.

■ 4. In § 35.13, revise paragraph (b)(4) to read as follows:

§ 35.13 License amendments.

(b) * * *

(4) An individual who is identified as an authorized user, an authorized nuclear pharmacist, authorized medical physicist, or an ophthalmic physicist—

(i) On a Commission or Agreement State license or other equivalent permit or license recognized by NRC that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(ii) On a permit issued by a Commission or Agreement State specific license of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(iii) On a permit issued by a Commission master material licensee that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy; or

(iv) By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists;

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

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

Authority: Atomic Energy Act of 1954, secs. 11, 101, 102, 103, 104, 105, 108, 122, 147, 149, 161, 181, 182, 183, 184, 185, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2131, 2132, 2133, 2134, 2135, 2138, 2152, 2167, 2169, 2201, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202,

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

§ 50.75 [Amended]

■ 6. In § 50.75, amend paragraph (e)(1)(ii)(A) by removing the text "foregoing,that" and adding in its place the text "foregoing, that".

PART 51—ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

■ 7. The authority citation for part 51 continues to read in part as follows:

Authority: Atomic Energy Act of 1954, secs. 161, 193 (42 U.S.C. 2201, 2243); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); National Environmental Policy Act of 1969 (42 U.S.C. 4332, 4334, 4335); Nuclear Waste Policy Act of 1982, secs. 144(f), 121, 135, 141, 148 (42 U.S.C. 10134(f), 10141, 10155, 10161, 10168); 44 U.S.C. 3504 note.

■ 8. In § 51.4, remove the definition of *NRC Staff Director* and add the definition *NRC staff director* in its place to read as follows:

§51.4 Definitions.

* * * * * *

NRC staff director means the Executive Director for Operations; the Director, Office of Nuclear Reactor Regulation; the Director, Office of Nuclear Material Safety and Safeguards; the Director, Office of Nuclear Regulatory Research; the Director, Office of Public Affairs; and the designee of any NRC staff director.

PART 52—LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS

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

Authority: Atomic Energy Act of 1954, secs. 103, 104, 147, 149, 161, 181, 182, 183, 185, 186, 189, 223, 234 (42 U.S.C. 2133, 2134, 2167, 2169, 2201, 2231, 2232, 2233, 2235, 2236, 2239, 2273, 2282); Energy

Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); 44 U.S.C. 3504 note.

§ 52.17 [Amended]

■ 10. In footnote 2 to § 52.17, remove the text "an accidents" and add in its place the text "an accident".

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

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

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

■ 12. In § 72.214, revise Certificate of Compliance No. 1029 to read as follows:

§ 72.214 List of approved spent fuel storage casks.

Certificate Number: 1029. Initial Certificate Effective Date: February 5, 2003, superseded by Renewed Initial Certificate on October

Amendment Number 1 Effective Date: May 16, 2005, superseded by Renewed Amendment Number 1 on October 27, 2021.

Amendment Number 2 Effective Date: Amendment not issued by the NRC.

Amendment Number 3 Effective Date: February 23, 2015, superseded by Renewed Amendment Number 3 on October 27, 2021.

Amendment Number 4 Effective Date: March 12, 2019, superseded by Renewed Amendment Number 4 on October 27, 2021. SAR Submitted by: Transnuclear, Inc., now TN Americas, LLC.

Renewal SAR Submitted by: TN Americas, LLC.

SAR Title: Final Safety Analysis Report for the Standardized Advanced NUHOMS® Horizontal Modular Storage System for Irradiated Nuclear Fuel.

Docket Number: 72-1029.

Certificate Expiration Date: February 5, 2023.

Renewed Certificate Expiration Date: February 5, 2063.

Model Number: Standardized Advanced NUHOMS®-24PT1, -24PT4, and -32PTH2.

* * * * *

PART 73—PHYSICAL PROTECTION OF PLANTS AND MATERIALS

■ 13. The authority citation for part 73 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 147, 149, 161, 170D, 170E, 170H, 170I, 223, 229, 234, 1701 (42 U.S.C. 2073, 2167, 2169, 2201, 2210d, 2210e, 2210h,

2210i, 2273, 2278a, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

Section 73.37(b)(2) also issued under sec. 301, Pub. L. 96–295, 94 Stat. 789 (42 U.S.C. 5841 note).

■ 14. In appendix A to part 73, revise the fifth entry in the first table to read as follows:

Appendix A to Part 73—U.S. Nuclear Regulatory Commission Offices and Classified Mailing Addresses

Address

Telephone (24 hour)

Email

Region IV: Alaska, Arizona, Arkansas, California, Colorado, Hawaii, Idaho, Kansas, Louisiana, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Utah, Washington, Wyoming, and the U.S. territories and possessions in the Pacific.

US NRC, Region IV, 1600 E Lamar Blvd., Arlington, TX 76011–4511. (817) 200-1100, (800) 952-9677, TDD: (301) 415-5575. RidsRgn4MailCenter@ nrc.gov.

PART 110—EXPORT AND IMPORT OF NUCLEAR EQUIPMENT AND

MATERIAL

■ 15. The authority citation for part 110 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 51, 53, 54, 57, 62, 63, 64, 65, 81, 82, 103, 104, 109, 111, 121, 122, 123, 124, 126, 127, 128, 129, 133, 134, 161, 170H, 181, 182, 183, 184, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2071, 2073, 2074, 2077, 2092, 2093, 2094, 2095, 2111, 2112, 2133, 2134, 2139, 2141, 2151, 2152, 2153, 2154, 2155, 2156, 2157, 2158, 2160c, 2160d, 2201, 2210h, 2231, 2232, 2233, 2234, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); Administrative Procedure Act (5 U.S.C. 552, 553); 42 U.S.C. 2139a, 2155a; 44 U.S.C. 3504

Section 110.1(b) also issued under 22 U.S.C. 2403; 22 U.S.C. 2778a; 50 App. U.S.C. 2401 *et seq*.

■ 16. In § 110.22, add paragraph (a)(4) to read as follows:

§ 110.22 General license for the export of source material.

(a) * * *

(4) A general license is issued to any person to export uranium, enriched to less than 20 percent in U–235, in the form of UF6 heels in cylinders being returned to suppliers in EURATOM or the United Kingdom.

* * * * *

PART 150—EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

■ 17. The authority citation for part 150 continues to read in part as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 53, 81, 83, 84, 122, 161, 181, 223, 234, 274 (42 U.S.C. 2014, 2201, 2231, 2273, 2282, 2021); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

■ 18. In § 150.15:

■ a. Amend paragraphs (a)(7)(iii) and (a)(8) by removing the text "under part 50 of this chapter" and adding in its place the text "under part 50 or 52 of this chapter"; and

■ b. Add paragraph (a)(9). The addition reads as follows:

§150.15 Persons not exempt.

(a) * * *

(9) The requirements for the protection of Safeguards information in § 73.21 of this chapter and the requirements in § 73.22 or § 73.23 of this chapter, as applicable.

* * * * *

Dated: November 7, 2022. For the Nuclear Regulatory Commission. Cindy K. Bladey,

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

[FR Doc. 2022–24614 Filed 11–10–22; 8:45 am]

BILLING CODE 7590-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1239

[Docket No. CPSC-2019-0014]

Safety Standard for Gates and Enclosures

AGENCY: Consumer Product Safety Commission.

ACTION: Direct final rule.

SUMMARY: Consistent with the CPSIA's process for updating mandatory standards for durable infant or toddler products that are based on a voluntary standard, this direct final rule updates the mandatory standard for gates and enclosures to incorporate by reference to ASTM F1004–22.

DATES: The rule is effective on January 21, 2023, unless CPSC receives a significant adverse comment by December 14, 2022. If CPSC receives such a comment, it will publish a notification in the **Federal Register**, withdrawing this direct final rule before its effective date. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of January 21, 2023.

ADDRESSES: You can submit comments, identified by Docket No. CPSC-2019-0014, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: www.regulations.gov. Follow the instructions for submitting comments. CPSC typically does not accept comments submitted by electronic mail (email), except as described below. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal.

Mail/hand delivery/courier Written Submissions: Submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: cpsc-os@cpsc.gov.

Instructions: All submissions must include the agency name and docket number. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: www.regulations.gov. Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier/ confidential written submissions.

Docket: For access to the docket to read background documents or comments received, go to: www.regulations.gov, and insert the docket number, CPSC-2019-0014, into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT:

Carlos Torres, Project Manager, Division of Mechanical and Combustion Engineering, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 987–2504; email: ctorres@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

1. Statutory Authority

Section 104(b)(1) of the CPSIA requires the Commission to assess the effectiveness of voluntary standards for durable infant or toddler products and to adopt mandatory standards for these products. 15 U.S.C. 2056a(b)(1). A mandatory standard must be "substantially the same as" the corresponding voluntary standard, or it may be "more stringent than" the voluntary standard, if the Commission determines that more stringent requirements would further reduce the

risk of injury associated with the product. *Id*.

Section 104(b)(4)(B) of the CPSIA specifies a process for updating the Commission's rules when a voluntary standards organization revises a standard that the Commission previously incorporated by reference under section 104(b)(1). First, the voluntary standards organization must notify the Commission of the revision. Once the Commission receives this notification, the Commission may reject or accept the revised standard. The Commission may reject the revised standard by notifying the voluntary standards organization, within 90 days of receiving notice of the revision, that it has determined that the revised standard does not improve the safety of the consumer product and that it is retaining the existing standard. If the Commission does not take this action to reject the revised standard, the revised voluntary standard will be considered a consumer product safety standard issued under section 9 of the Consumer Product Safety Act (15 U.S.C. 2058), effective 180 days after the Commission received notification of the revision or on a later date specified by the Commission in the **Federal Register**. 15 U.S.C. 2056a(b)(4)(B).

2. Safety Standard for Gates and Enclosures

Under section 104(b)(1) of the CPSIA, the Commission adopted a mandatory rule for gates and enclosures, codified in 16 CFR part 1239. The rule incorporated by reference ASTM F1004–19, Standard Consumer Safety Specification for Expansion Gates and Expandable Enclosures, with two modifications. 85 FR 40100 (July 6, 2020). The standard is intended to address head and neck entrapment in children's expansion gates and expandable enclosures, and the ability of pressure gates to resist a push-out force.

In 2021, ASTM revised the voluntary standard to align with the two modifications contained in 16 CFR part 1239, by adding the following requirements for pressure-mounted gates:

• For pressure-mounted gates that rely on wall cups to meet the 30-lb push-out force test, the gates must include a separate warning label (regarding correct installation) in a conspicuous location on the top rail; or

• For pressure-mounted gates that do not use wall cups, the gates must use visual side-pressure indicators to provide feedback on whether the gate is installed correctly.

Because the revised voluntary standard aligned with the mandatory

standard, the Commission published a direct final rule on September 28, 2021, to update 16 CFR part 1239 to reflect incorporation by reference of ASTM F1004–21, with no modifications (86 FR 53535).

On June 1, 2022, ASTM approved and published a further revision, ASTM F1004–22. ASTM notified CPSC of the revision on July 25, 2022. On August 4, 2022, the Commission published a Notice of Availability in the **Federal Register**, requesting comment on whether the revision improves the safety of gates and expandable enclosures (87 FR 47729). Public comment closed on August 18, 2022, and CPSC did not receive any comments.

As discussed in section B. Revisions to ASTM F1004, based on CPSC staff's review of ASTM F1004-22.1 the Commission will allow the revised voluntary standard to become the mandatory standard.2 Accordingly, by operation of law under section 104(b)(4)(B) of the CPSIA, ASTM F1004-22 will become the mandatory consumer product safety standard for gates and enclosures on January 21, 2023. 15 U.S.C. 2056a(b)(4)(B). This direct final rule updates 16 CFR part 1239 to incorporate by reference the revised voluntary standard, ASTM F1004-22.

B. Revisions to ASTM F1004

The ASTM standard for gates and enclosures includes performance requirements, test methods, and requirements for marking, labeling, and instructional literature, to address hazards to children associated with expandable gates and enclosures. The CPSC's current mandatory standard Safety Standards for Gates and Enclosures in 16 CFR part 1239 incorporates by reference ASTM F1004–21, with no modifications.

The revision to ASTM F1004–22 consists of changes to the illustrated examples of warning labels referenced as Figures in Section 8.4.7. The warning statement: "You MUST install wall cups to keep the gate in place. Without wall cups, child can push out and escape" was removed from Figures 8 through 10, and the same warning statement is shown as a standalone label in a new Figure 11. This change reflects the requirement in Section 8.5.7 for pressure-mounted gates to have a separate warning, specific to installation of wall cups, if the design of that gate

 $^{^{1}\,\}mbox{CPSC}$ staff's briefing package regarding ASTM F1004–22 is available at: [INSERT LINK].

² The Commission voted TBD-TBD to approve this notice

relies on the wall cups to meet the pushout force requirements.

A WARNING

You MUST install wall cups to keep the gate in place. Without wall cups, child can push out and escape.

FIG. 11 Example Separate Wall Cup Installation Warning

Under section 104(b)(4)(B) of the CPSIA, unless the Commission notifies ASTM that it's revision to a voluntary standard that is referenced in a mandatory standard "does not improve the safety of the consumer product covered by the standard," the revised voluntary standard becomes the new mandatory standard. The Commission determines that the substantive change in the latest revision to ASTM F1004 is an improvement to safety of the product.

When ASTM F1004 was updated in 2021 to align with CPSC's mandatory standard for gates and enclosures, the standard added the following requirement, specific to pressuremounted gates:

• 8.5.7 Pressure-mounted gates that provide wall cups or other mounting hardware to meet the requirements of 6.3 shall have the following warning in the location specified: You MUST install [wall cups] to keep gate in place. Without [wall cups], child can push out and escape.

• 8.5.7.1 This warning shall be separate from all other warnings required on the product and shall not include any additional language.

However, the illustrated examples of warnings shown in Figures 8 through 10 were not updated to reflect that a separate warning label specific to installing wall cups is required for pressure-mounted gates that rely on such hardware to withstand push-out forces. The examples of warning labels in ASTM F1004-21 continue to show the statements to install wall cups ("You MUST install wall cups to keep the gate in place. Without wall cups, child can push out and escape.") alongside other warning statements. The revised standard corrects the illustrated examples to reflect that specific requirement in Section 8.5.7 that warnings to install wall cups must be conveyed in a separate, standalone warning label.

This change aligns the exemplar warning labels with language in the standard emphasizing that pressuremounted gates that rely on wall cups to meet the horizontal push-out requirements must clearly warn the consumer that the wall cups must be

installed for the product to function properly. The standard requires a separate, standalone statement, and the examples of illustrated warning labels now reflect that standalone warning. The Commission concludes the change is an improvement to safety because it reinforces a message that is critical to the safe use of the product and provides an example that firms could use to meet the standard that is consistent with the requirement in the standard.

C. Incorporation by Reference

Section 1239.2 of the direct final rule incorporates by reference ASTM F1004–22. The Office of the Federal Register (OFR) has regulations regarding incorporation by reference. 1 CFR part 51. Under these regulations, agencies must discuss, in the preamble to a final rule, ways in which the material the agency incorporates by reference is reasonably available to interested parties, and how interested parties can obtain the material. In addition, the preamble to the final rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR regulations, section B. Revisions to ASTM F1004 of this preamble summarizes the major provisions of ASTM F1004–22 that the Commission incorporates by reference into 16 CFR part 1239. The standard itself is reasonably available to interested parties. Until the direct final rule takes effect, a read-only copy of ASTM F1004–22 is available for viewing, at no cost, on ASTM's website at: https:// www.astm.org/CPSC.htm. Once the rule takes effect, a read-only copy of the standard will be available for viewing, at no cost, on the ASTM website at: https://www.astm.org/ READINGLIBRARY/. Interested parties can also schedule an appointment to inspect a copy of the standard at CPSC's Office of the Secretary, U.S. Consumer

READINGLIBRARY/. Interested parties can also schedule an appointment to inspect a copy of the standard at CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, telephone: (301) 504–7479; email: cpsc-os@cpsc.gov. Interested parties can purchase a copy of ASTM F2088–22 from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959 USA;

telephone: (610) 832–9585; www.astm.org.

D. Certification

Section 14(a) of the Consumer Product Safety Act (CPSA; 15 U.S.C. 2051-2089) requires manufacturers of products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, to certify that the products comply with all applicable CPSC requirements. 15 U.S.C. 2063(a). Such certification must be based on a test of each product, or on a reasonable testing program, or for children's products, on tests of a sufficient number of samples by a third party conformity assessment body accredited by CPSC to test according to the applicable requirements. As noted, standards issued under section 104(b)(1)(B) of the CPSIA are "consumer product safety standards." Thus, they are subject to the testing and certification requirements of section 14 of the CPSA.

Because expandable gates and enclosures are children's products, a CPSC-accepted third party conformity assessment body must test samples of the products. Products subject to part 1239 also must comply with all other applicable CPSC requirements, such as the lead content requirements in section 101 of the CPSIA,³ the tracking label requirements in section 14(a)(5) of the CPSA,⁴ and the consumer registration form requirements in section 104(d) of the CPSIA.⁵ ASTM F1004–22 makes no changes that would impact any of these existing requirements.

E. Notice of Requirements

In accordance with section 14(a)(3)(B)(vi) of the CPSA, the Commission previously published a notice of requirements (NOR) for accreditation of third party conformity assessment bodies for testing gates and enclosures. 85 FR 40100 (July 6, 2020). The NOR provided the criteria and process for CPSC to accept accreditation of third party conformity assessment bodies for testing gates and enclosures

³ 15 U.S.C. 1278a.

^{4 15} U.S.C. 2063(a)(5).

⁵ 15 U.S.C. 2056a(d).

to 16 CFR part 1239. The NORs for all mandatory standards for durable infant or toddler products are listed in the Commission's rule, "Requirements Pertaining to Third Party Conformity Assessment Bodies," codified in 16 CFR part 1112. *Id*.

ASTM F1004-22 did not change the testing requirements, testing equipment, or testing protocols for gates and enclosures. Accordingly, the revisions do not change the way that third party conformity assessment bodies test these products for compliance with the safety standard for gates and enclosures. Testing laboratories that have demonstrated competence for testing in accordance with ASTM F1004-21 are competent to test in accordance with the revised standard ASTM F1004-22. Laboratories will begin testing to the new standard when ASTM F1004–22 goes into effect, and the existing accreditations that the Commission has accepted for testing to this standard will cover testing to the revised standard. Therefore, the Commission considers the existing CPSC-accepted laboratories for testing to ASTM F1004-21 to be capable of testing to ASTM F1004-22 as well. Accordingly, the existing NOR for this standard will remain in place, and CPSC-accepted third party conformity assessment bodies are expected to update the scope of the testing laboratories' accreditations to reflect the revised standard in the normal course of renewing their accreditations.

F. Direct Final Rule Process

On August 4, 2022, the Commission provided notice in the Federal Register of the revision to the standard and requested comment on whether the revision improves the safety of gates and enclosures covered by the standard. 87 FR 47729. No comments were submitted. Now, the Commission is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA; 5 U.S.C. 551-559) generally requires agencies to provide notice of a rule and an opportunity for interested parties to comment on it, section 553 of the APA provides an exception when the agency "for good cause finds" that notice and comment are "impracticable, unnecessary, or contrary to the public interest." Id. 553(b)(B). The Commission concludes that when it updates a reference to an ASTM standard that the Commission incorporated by reference under section 104(b) of the CPSIA, further notice and comment are unnecessary.

Specifically, under the process set out in section 104(b)(4)(B) of the CPSIA, when ASTM notifies CPSC that it has revised a standard that the Commission

has previously incorporated by reference under section 104(b)(1)(B) of the CPSIA, that revision will become the new CPSC standard, unless the Commission determines that ASTM's revision does not improve the safety of the product. Thus, unless the Commission makes such a determination, the ASTM revision becomes CPSC's standard by operation of law. The Commission is allowing ASTM F1004–22 to become CPSC's new standard because its provisions improve the safety of the product. The purpose of this direct final rule is to update the Code of Federal Regulations (CFR) so that it reflects the version of the standard that takes effect by statute. This rule updates the reference in the CFR, but under the CPSIA, ASTM F1004-22 takes effect as the new CPSC standard for gates and enclosures, even if the Commission does not issue this rule. Thus, public comments would not alter substantive changes to the standard or the effect of the revised standard as a consumer product safety standard under section 104(b) of the CPSIA. Under these circumstances, further notice and comment are unnecessary.

In Recommendation 95–4, the Administrative Conference of the United States (ACUS) endorses direct final rulemaking as an appropriate procedure to expedite rules that are noncontroversial and not expected to generate significant adverse comments. See 60 FR 43108 (Aug. 18, 1995). ACUS recommends that agencies use the direct final rule process when they act under the "unnecessary" prong of the good cause exemption in 5 U.S.C. 553(b)(B). Consistent with the ACUS recommendation, the Commission is publishing this rule as a direct final rule, because CPSC does not expect any significant adverse comments.

Unless CPSC receives a significant adverse comment within 30 days of this notification, the rule will become effective on January 21, 2023. In accordance with ACUS's recommendation, the Commission considers a significant adverse comment to be "one where the commenter explains why the rule would be inappropriate," including an assertion challenging "the rule's underlying premise or approach," or a claim that the rule "would be ineffective or unacceptable without a change." 60 FR 43108, 43111 (Aug. 18, 1995). As noted, this rule merely updates a reference in the CFR to reflect a change that occurs by statute, and public comments should address this specific action.

If the Commission receives a significant adverse comment, the Commission will withdraw this direct

final rule. Depending on the comment and other circumstances, the Commission may then incorporate the adverse comment into a subsequent direct final rule or publish a notice of proposed rulemaking, providing an opportunity for public comment.

G. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA; 5 U.S.C. 601-612) generally requires agencies to review proposed and final rules for their potential economic impact on small entities, including small businesses, and prepare regulatory flexibility analyses. 5 U.S.C. 603, 604. The RFA applies to any rule that is subject to notice and comment procedures under section 553 of the APA. *Id.* As discussed in section F. Direct Final Rule Process of this preamble, the Commission has determined that further notice and the opportunity to comment are unnecessary for this rule. Therefore, the RFA does not apply. CPSC also notes the limited nature of this document, which merely updates the incorporation by reference to reflect the mandatory CPSC standard that takes effect under section 104 of the CPSIA.

H. Paperwork Reduction Act

The current mandatory standard for gates and enclosures includes requirements for marking, labeling, and instructional literature that constitute a "collection of information," as defined in the Paperwork Reduction Act (PRA; 44 U.S.C. 3501–3521). While the revised mandatory standard revises the labeling language for gates and enclosures, the revised language would not add to the burden hours because the products already require marking, labeling, and instructional literature under the current standard. The revised labeling provisions merely require different language to that already required by the standard, which would impose minimal if any additional burden because the firm is already required to put labels on the product. The Commission took the steps required by the PRA for information collections when it promulgated 16 CFR part 1223, and the marking, labeling, and instructional literature for gates and enclosures are currently approved under OMB Control Number 3041-0159. Because the information collection burden is unchanged, the revision does not affect the information collection requirements or approval related to the standard.

I. Environmental Considerations

The Commission's regulations provide a categorical exclusion for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement where they "have little or no potential for affecting the human environment." 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

J. Preemption

Section 26(a) of the CPSA provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. 15 U.S.C. 2075(a). Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to CPSC for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA deems rules issued under that provision "consumer product safety standards." Therefore, once a rule issued under section 104 of the CPSIA takes effect, it will preempt in accordance with section 26(a) of the CPSA.

K. Effective Date

Under the procedure set forth in section 104(b)(4)(B) of the CPSIA, when a voluntary standards organization revises a standard that the Commission adopted as a mandatory standard, the revision becomes the CPSC standard within 180 days of notification to the Commission, unless the Commission timely notifies the standards organization that it has determined that the revision does not improve the safety of the product, or the Commission sets a later date in the Federal Register. 15 U.S.C. 2056a(b)(4)(B). The Commission is taking neither of those actions with respect to the standard for gates and enclosures. Therefore, ASTM F1004-22 will take effect as the new mandatory standard for gates and enclosures on January 21, 2023, 180 days after July 25, 2022, when the Commission received notice of the revision.

L. Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801–808) states that before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The CRA submission must indicate whether the rule is a "major rule." The CRA states

that the Office of Information and Regulatory Affairs determines whether a rule qualifies as a "major rule."

Pursuant to the CRA, this rule does not qualify as a "major rule," as defined in 5 U.S.C. 804(2). To comply with the CRA, CPSC will submit the required information to each House of Congress and the Comptroller General.

List of Subjects in 16 CFR Part 1239

Consumer protection, Imports, Incorporation by reference, Infants and children, Law enforcement, Safety.

For the reasons discussed in the preamble, the Commission amends 16 CFR chapter II as follows:

PART 1239—SAFETY STANDARD FOR GATES AND ENCLOSURES

■ 1. The authority citation for part 1239 continues to read as follows:

Authority: 15 U.S.C. 2056a.

■ 2. Revise § 1239.2 to read as follows:

§ 1239.2 Requirements for gates and enclosures.

Each gate and enclosure must comply with all applicable provisions of ASTM F1004-22. Standard Consumer Safety Specification for Expansion Gates and Expandable Enclosures, approved on June 1, 2022. 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. A read-only copy of the standard is available for viewing on the ASTM website at https:// www.astm.org/READINGLIBRARY/. You may obtain a copy from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959; telephone (610) 832-9585; www.astm.org. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, telephone (301) 504-7479, email cpsc-os@cpsc.gov, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fr.inspection@nara.gov, or go to: www.archives.gov/federal-register/cfr/ ibr-locations.html.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2022–24561 Filed 11–10–22; 8:45 am]

BILLING CODE 6355-01-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301, 1309, and 1316 [Docket No. DEA-438]

RIN 1117-AB36

Default Provisions for Hearing Proceedings Relating to the Revocation, Suspension, or Denial of a Registration

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is amending its regulations by adding and revising provisions which enable DEA to hold registrants or applicants in default when they fail to timely request a hearing, or otherwise fail to participate in hearings. DEA is also amending its regulations to include an answer provision which will regulate how registrants respond to an Order to Show Cause (OTSC). These changes involve the revocation, suspension, or denial of a registration and do not affect other types of hearings.

DATES: This final rule is effective 30 days from November 14, 2022.

FOR FURTHER INFORMATION CONTACT:

Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

I. Background

A. Regulatory History

DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and the Controlled Substances Import and Export Act (21 U.S.C. 801-971), as amended, and referred to as the Controlled Substances Act (CSA).¹ The CSA is designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for a sufficient supply of controlled substances and listed chemicals for legitimate medical, scientific, research, and industrial purposes. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety. To this end, controlled substances are classified into one of five schedules

 $^{^{1}}$ The Attorney General's delegation of authority to DEA may be found at 28 CFR 0.100.

based upon: the potential for abuse, currently accepted medical use, and the degree of dependence if abused. 21 U.S.C. 812. Listed chemicals are separately classified based on their use in and importance to the manufacture of controlled substances (list I or list II chemicals). 21 U.S.C. 802(33)–(35).

In accordance with the Attorney General's authority to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions" under the Act, 21 U.S.C. 871(b), DEA's predecessor agency, the Department of Justice's Bureau of Narcotics and Dangerous Drugs, first issued regulations in 1971 to implement the Comprehensive Drug Abuse Prevention and Control Act of 1970, which included administrative hearing provisions.2 With a few exceptions, the administrative hearing provisions of those 1971 regulations are virtually identical to the ones in place today.

The changes in this action apply only to hearings relating to the denial, revocation, or suspension of a DEA registration pursuant to 21 U.S.C. 823, 824, and 958. This rule does not implement changes for any other type of hearings that DEA may conduct, including hearings relating to quota issuance, revision, or denial, or those relating to the scheduling of controlled substances.

B. Existing Regulations

The general administrative hearing provisions which apply to all hearings brought pursuant to 21 U.S.C. 823, 824 and 958 are found at 21 CFR part 1316, subpart D. Specific administrative hearing provisions relating to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances are in 21 CFR 1301.32, 1301.34-37, and 1301.41-46, as well as 21 CFR 1316.41-68. Administrative hearing provisions relating to the registration of manufacturers, distributors, importers, and exporters of list I chemicals are in 21 CFR 1309.42, 1309.43, 1309.46, 1309.51-55, and 21 CFR 1316.41-68.

In contrast to the hearing regulations of many other federal agencies, current DEA regulations contained in 21 CFR parts 1301, 1309, and 1316 relating to actions to deny, suspend, or revoke a DEA registration do not contain a responsive pleading to an OTSC (*i.e.*, an answer provision) or a default provision. The changes in this final rule

apply only to hearings relating to the denial, revocation, or suspension of a DEA registration pursuant to 21 U.S.C. 823, 824, and 958. This rulemaking does not amend any other type of hearings regulations that DEA may conduct, including hearings relating to quota issuance, scheduling of controlled substances, etc.

II. Purpose and Need for Rulemaking

DEA is revising its regulations by adding new provisions to increase the efficiency of, and facilitate the processing of, its administrative hearings. In the current practice, the lack of an answer provision or default provision resulted in agency inefficiencies where litigants waive their right to a hearing or otherwise fail to participate in the administrative hearing process. DEA is promulgating several new provisions for the purpose of mitigating the issues of litigants failing to participate generally in the administrative process.

A. Need for New Provisions

DEA needs to revise its regulations in order to expedite the administrative hearing process as the current provisions may cause administrative waste for DEA and potential delays for registrants. First, the lack of a default provision has led to excessive extension requests in circumstances where the registrant eventually decides to not request a hearing. Additionally, the lack of clear provisions regarding responsive pleadings has led to confusion and inefficiency, and it unnecessarily slowed down the administrative hearing process.

The absence of a default provision has led to inefficiencies in circumstances where DEA prepared extensively for hearings that never occurred, or occurred later than they should due to respondents not complying with orders in the case. Respondents presently are permitted 30 days to request a hearing upon receipt of an OTSC. If a request for an extension was granted by the presiding officer, this gives respondents up to an additional 30 to 60 days to respond. DEA could thus be preparing for litigation for up to 90 days under some circumstances, which is excessively long for the filing of a request for hearing. This problem is exacerbated in light of the absence of any default provision, as DEA could be preparing for litigation for 90 days in cases where no hearing is actually requested.

Furthermore, as noted, DEA regulations currently have no default provision which permits the government's (or respondent's) entry of

default upon a litigant's failure to participate. Additionally, if respondents fail to otherwise participate in the hearing process, DEA must submit an entry for final order to the Administrator. This final order requires a voluminous record providing evidence in support of every factual allegation that was included in the OTSC. This results in a very large time and resource investment for DEA to review the record and draft the final order.

Last, DEA lacks a comprehensive set of rules for responsive pleadings, or the answer. The existing rules are unclear what the answer should contain, thus resulting in ambiguity for the general public (pro se litigants in particular). As a result, DEA occasionally receives responsive pleadings that were incomplete or insufficient, thus leading to an unnecessary delay of the administrative process. Furthermore, the regulations lack a provision dictating what happens procedurally should the respondent fail to file an answer. Thus, DEA needs amendments to its administrative hearing regulations in the form of adding default provisions and updating responsive pleading rules.

B. Purpose and Description of Changes

DEA is amending its administrative hearing regulations by adding certain provisions and revising other provisions to increase the efficiency of the administrative hearing process. As stated above, these changes are necessary to prevent the unnecessary expenditure of agency resources, to clarify obligations, and to expedite the hearing process for both parties. The changes in this action apply only to hearings relating to the denial, revocation, or suspension of a DEA registration pursuant to 21 U.S.C. 823, 824, and 958. Again, this rulemaking does not contemplate changes for any other types of hearings that DEA may conduct, such as hearings relating to the scheduling of controlled substances, quota issuance, etc.

15 Days To Request a Hearing

In the Notice of Proposed Rulemaking (NPRM), DEA had proposed to revise the existing regulations to decrease the deadline for submitting a request for a hearing from the current 30 days to 15 days. In light of the public comments and upon further consideration of the issues, DEA has decided to maintain the current deadline for requesting a hearing and the final rule retains the 30-day deadline after receipt of the OTSC for submitting a request for a hearing.

As a result of this decision, DEA is thus revising the provisions pertaining to this deadline as follows: 21 CFR

² See Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970, 36 FR 7776 (Apr. 24, 1971).

1301.37(d) by adding paragraph (1); ³ § 1309.46(d) by adding paragraph (1); and § 1316.47 by amending paragraphs (a) and (b). These changes reflect the requirement of respondents, should they desire to contest the OTSC, to file a request for a hearing in response to an OTSC within 30 days of receipt of the OTSC.4 DEA believes these changes will achieve the desired ends of administrative efficiency while not materially changing the burden of respondents as the time in which to request a hearing is not changed. Allowing 30 days for requesting a hearing is consistent with the 30-day time period for respondents to file an answer.

Filing an Answer

DEA is amending the following provisions, which require that respondents who request a hearing will file an answer to the OTSC within 30 days of the receipt of the OTSC: § 1301.37(d) by adding paragraph (2); § 1309.46(d) by adding paragraph (2); and § 1316.47 by revising paragraph (b).

First, § 1301.37(d)(2) permits the presiding officer, the Administrative Law Judge, to consider an answer that was filed after the deadline upon a showing of good cause. DEA anticipates that, in contrast to simply requesting a hearing, preparing an answer will take more time and effort than simply requesting a hearing. Thus, DEA believes the 30-day requirement to file an answer, with a good cause provision in the event of delay, is sufficiently tailored to balance the needs of the public with the interest in administrative efficiency.

Next, DEA is amending § 1301.37(d) by adding paragraph (3), and § 1309.46(d) by adding paragraph (3). These provisions require respondents to admit, deny, or state they are unable to answer each factual allegation contained in the OTSC. It also provides that any allegation not denied shall be deemed admitted. This addition is necessary to clarify the requirements of an answer to the general public, in order to limit the scope of the proceeding to issues which are genuinely in dispute. Last, DEA is amending § 1301.37(d) by adding

paragraph (4), and § 1309.46(d) by adding paragraph (4), which state that a party may amend its answer as a matter of right once before the prehearing ruling. These provisions also grant the presiding officer leave to permit amendments to the answer as justice so requires.

The changes to these provisions are needed to clarify, to the general public, when and under what circumstances an answer is required. As stated, prior to adopting this rule it has been unclear to respondents when and under what circumstances an answer must be filed, and what must be contained in the answer. These changes elucidate exactly when an answer is required and what must be contained, and grant authority to the presiding officer to make exceptions when merited.

Default Provisions

DEA is amending its regulations to permit the entry of default where a party fails to timely request a hearing, or fails to participate in the administrative hearing process. DEA is amending its regulations by revising § 1301.43(c)(1) and § 1309.53(b)(1),5 to permit DEA's entry of default where the respondent fails to timely request a hearing in response to an OTSC. Respondents who fail to request a hearing are nevertheless able to waive the default by filing a motion with the Office of Administrative Law Judges within 45 days after the date of receipt of the OTSC. The presiding officer may rule on the motion timely filed within 45 days, and may waive the default after the 45day period lapsed. The presiding officer is authorized to grant the motion. DEA believes this rule is necessary to prevent administrative waste while also providing sufficient discretion for the presiding officer to nevertheless permit a hearing in circumstances which merit

Under this rule, once a registrant is in default for failure to timely file a request for a hearing or file an answer, this means that the respondent is deemed to agree to all of the factual allegations in the OTSC.⁶ Without this provision, DEA would be required to prepare an administrative record providing evidence sufficient to support every factual allegation in the OTSC, regardless of whether the respondent wishes to contest those allegations or

whether, had he so contested, he would have challenged every factual allegation.

Next, DEA is amending its regulations by adding several instances where a party can be held in default for generally failing to participate in the administrative hearing process. First, DEA is adding § 1301.43(c)(2), as well as § 1309.53(b)(2), which state that respondents who request a hearing, but fail to timely file an answer (and fail to demonstrate good cause) are considered to have waived their opportunity for a hearing and are in default. Once a party is held in default for failing to timely file an answer and fails to establish good cause, the presiding officer is required to enter an order terminating the proceedings once DEA files a motion. Moreover, DEA is adding § 1301.43(c)(3), as well as § 1309.53(b)(3), which states a party shall also be in default for failing to plead or otherwise defend. Upon motion, the presiding officer must enter an order terminating the proceeding unless the party can demonstrate good cause to stay the order. After termination of the proceeding, a party may also file a motion to excuse default with the Office of the Administrator.

DEA is amending its regulations by revising § 1301.43(e) and 1309.53(d) to state that in all instances of default, the party's default shall be deemed to constitute a waiver of their right to a hearing, and an admission of the factual allegations of the order to show cause. Moreover, DEA is amending its regulations by adding $\S 1301.43(f)(1)$ –(3) and § 1309.53(e)(1)-(3), which specify the required procedure to follow once a respondent is in default. Once a respondent is in default, and the presiding officer has issued an order terminating the proceedings, DEA may file a request for a final agency action with the Administrator. Respondents have the right to appeal either the termination of proceeding or the final order by following the procedures contained therein.

The aforementioned provisions allow the entry of default in circumstances in which the respondent essentially waives their right and opportunity to participate in the hearing process by failing to request a hearing, failing to respond, or otherwise failing to participate. These provisions are necessary, as DEA is needlessly expending significant resources in common circumstances where the respondent fails to litigate. Under the default provisions in this final rule, this admission of the factual allegations of the OTSC in the event of default facilitates the enforcement process by eliminating the need for DEA to provide

³ This rule is revising 21 CFR 1301.37(d) (relating to controlled substance registrations) by replacing paragraph (d) with paragraphs (d)(1) through (d)(4). New paragraph (d)(1) relates to requests for hearings, and new paragraphs (d)(2) through (d)(4) relate to the filing and amendment of the answer. 21 CFR 1309.46(d) (relating to listed chemical registrations) is similarly being revised according to the same structure.

⁴Receipt by the registrant, for the purposes of this paragraph, will be determined by when the registrant receives the OTSC via certified mail at the location listed on the registration.

⁵ As mentioned above in the discussion of the answer and request for hearing provisions, part 1301 relates to controlled substance registrations, and part 1309 relates to listed chemical registrations.

⁶ See 21 CFR 1301.43(e), 1309.53(d).

evidentiary support for every factual allegation. DEA believes these provisions will preserve scarce agency resources by eliminating excess time and resources spent on cases where respondents fail to contest the allegations of the OTSC on the merits. Additionally, DEA believes that the procedures in place grant sufficient ability for respondents to appeal the actions of the presiding officer and the Administrator. Thus, DEA believes these provisions will substantially expedite the administrative hearing process while preserving respondents' due process rights.

Other

DEA is also amending its regulations by revising § 1316.49 to exclude respondents engaged in proceedings held under parts 1301 or 1309 from the ability to file a waiver of a hearing and a statement in lieu of a hearing. DEA believes that matters litigated under parts 1301 and 1309 are uniquely enhanced by the hearing setting, namely credibility determinations and resolutions of factual disputes. Thus, DEA is limiting this exception to only matters adjudicated under § 1301 or § 1309, and other proceedings continue to be eligible for the waiver.

These regulatory changes and this rulemaking generally apply only to OTSCs and associated hearings issued on or subsequent to the effective date listed above.

III. Public Comments on the NPRM

DEA received four comments during the 60-day comment period. All four commenters referenced § 1301.37(d)(1), stating that the 15-day time limit to request a hearing was too short. Two commenters referenced § 1301.37(2), arguing the 30-day time limit to file an answer was too short. One commenter referenced § 1309.46, arguing registrants should have up to three times to amend an answer as a matter of right. Last, one commenter argued that respondents engaged in proceedings under parts 1301 or 1309 should be permitted to submit a written statement in lieu of requesting a hearing.

DEA has closely reviewed and considered every comment and has decided for the following reasons to promulgate the regulations as drafted, with one change regarding the time limit for requesting a hearing.

15-Day Period for Requesting a Hearing, § 1301.37(d)(1)

The proposed rule would have required registrants to request a hearing within 15 days of receipt of an OTSC, instead of the 30 days allowed under the current regulations. This proposal received the most criticism during the comment period, as all commenters believe the 15-day requirement would generally be too prohibitive for registrants. Based on the comments from the public, DEA has decided not to adopt this provision from the proposed rule. The final rule permits registrants 30 days to request a hearing, rather than 15 days.

First, commenters generally stated the 15-day period is too short as it would not leave sufficient time to complete typical prehearing tasks. Specifically, commenters noted this was insufficient time to contact an attorney, contact and gather information from parties who may be involved, as well as investigate. Alternatively, the commenters proposed allowing 30-60 days to request a hearing because, according to their view, this would be sufficient time to prepare for a hearing. Moreover, one commenter argued that this short time period would lead to multiple requests for an extension, thereby contradicting the purpose of the new rule by further delaying the administrative process.

DEA Response: DEA has examined all comments related to this provision, and has decided to retain the existing 30-day period in this final rule to request a hearing, instead of shortening that period to 15 days. First, DEA believes this time period is reasonable, namely that this 30-day period provides sufficient time for the respondent to request a hearing. DEA understands and appreciates that the decision to request a hearing is often done after consulting with counsel to deliberate on the merits of the case; therefore, it makes sense to set the same 30-day deadline for requesting a hearing and for submission of an answer to the OTSC.

When drafting this rule, and after consideration of all the comments, DEA considered the option of providing registrants/applicants up to 60 days to request a hearing. Although this would provide the registrant/applicant maximum opportunity to evaluate all contingencies related to the hearing, DEA does not consider this necessary. This 30-day period should allow sufficient time for registrants/applicants to contact parties, conduct factual investigations, and otherwise prepare for the hearing should they choose to do so.

Requesting a hearing within this time period would eliminate a substantial amount of administrative waste, as most registrants who are served with an OTSC do not request a hearing. The provisions of this rule requiring the request for a hearing and the answer on the merits to both be filed within 30

days of the receipt of the OTSC will provide DEA a means of quickly and efficiently processing cases, as the majority will then be processed at an expedited pace. One commenter noted, and DEA agrees, that some cases will result in a request for an extension. DEA anticipates that this provision will, on balance, save more time by facilitating cases than will be lost by considering extension requests.

Last, DEA finds this provision reasonable and preserves the registrants' due process rights as it creates a means for registrants to file a motion to set aside default when good cause is shown within 45 days of the receipt of the OTSC. Thus, even in those circumstances where registrants are in default, they would be able to still request a hearing when good cause is shown.

30 Days To File Answer, § 1301.37(2)

DEA has closely reviewed all the comments relating to the requirement to file an answer in 30 days under § 1301.37(2) and has decided to promulgate the section as written. One commenter argued the requirement for a registrant to file an answer within 30 days of receipt of the OTSC is arbitrary, and does not permit sufficient time to contact parties involved or conduct factual investigations. Moreover, another commenter argued that 30 days is insufficient time to adequately respond to the OTSC, favoring 60 days instead.

DEA acknowledges that filing an answer will likely require more time and effort than simply requesting a hearing. DEA believes, however, the requirement to file an answer within 30 days is reasonable and sufficient time to adequately prepare a response to the OTSC.

First, requiring a response within such a time frame is commonplace among other administrative regulations as well as other state and federal level courts.7 Although there are important differences between administrative hearings and federal court cases, it is telling that the Federal Rules of Civil Procedure require a responsive pleading within 21 days of being served, which is 9 days less than what DEA rules require.8 Thus, even though the answer will likely require more time and effort than simply requesting a hearing, the time allotted is generous when compared to federal civil practice.

Moreover, as stated in the NPRM, this requirement will significantly improve efficiency by narrowing the scope of the

⁷ See 85 FR 61662, 61664.

⁸ Fed. R. Civ. P. 12(a)(A)(i).

factual issues to only that which is in genuine dispute. This efficiency will result in expediting cases significantly, benefitting both DEA and registrants.

Last, registrants are permitted to amend their answer should they choose, which cures many of the concerns raised by comments. DEA grants leave to amend the answer once as a matter of right under § 1309.46(d)(4), and permits the presiding offer to grant leave to amend. Thus, on balance, this provision allows DEA to process cases quickly and efficiently while enabling the registrants to adequately prepare for hearings.

Other Comments

DEA has closely reviewed all other comments and has decided to promulgate these regulations as written. First, one commenter stated the 30-day limit to file a motion to set aside default was too short, and should be 90 days. Another commenter stated that registrants should be able to amend their answer as a matter of right up to three times. Additionally, one commenter stated that requiring a hearing, rather than accepting a statement in lieu of requesting a hearing, creates administrative waste. Last, one commenter requested DEA to stay the proposed 15-day period to request a hearing until the COVID-19 pandemic is over.

First, as stated above, DEA believes the 45-day period to file motion to set aside default is reasonable and preserves the due process rights of registrants. In circumstances where registrants fail to request a hearing, they will then have 30 days from the entry of default to provide the presiding officer with an explanation as to why the request could not be filed. This safe harbor provision will enable registrants to set aside default where good cause is shown, and provide yet another opportunity for the registrant to present their case. Permitting 90 days to set aside default is unnecessary as this task only requires the filing of one motion. Moreover, this extended period would likely result in prolonging cases, contradicting the purpose and goal of default rules.

Next, DEA believes that granting leave to amend as a matter of right once, and subsequently granting the presiding officer the ability to amend when justice so requires, provides registrants sufficient opportunity to be heard. Granting leave to amend as a matter of right multiple times will likely result in a significant delay of processing cases. Registrants would then have no incentive to gather evidence, contact parties, prepare written statements, or

otherwise respond to DEA in a comprehensive manner the first time. Moreover, DEA creates a safe harbor by granting authority to the presiding officer to grant leave to amend in circumstances which are justified, such as when evidence was recently discovered and could not have been discovered prior to filing the original answer. Thus, DEA believes this provision is reasonable and preserves the registrant's due process rights.

DEA closely reviewed the comment regarding statements in lieu of hearings and has decided to promulgate the regulations as written. This commenter argues that the elimination of a statement in lieu of requesting a hearing would be wasteful for both DEA and the registrant in circumstances where the registrant has clearly exculpatory information. This, in theory, would remove the requirement for a hearing and would allow the expedited processing of that case. As stated previously, these hearings deal specifically with the revocation, suspension, or denial of a registration which is substantially benefitted by the presiding officer being able to resolve factual disputes and make credibility determinations. DEA believes that simply permitting a statement in lieu of this hearing would be a detriment to both DEA and respondents, and requiring a hearing would be optimal for both parties.

Last, DEA has closely reviewed the statements regarding the COVID-19 pandemic. As noted above, the final rule does not adopt the 15-day time limit proposed in the NPRM, and this final rule retains the existing 30-day deadline for filing a request for hearing. Although DEA is sympathetic to the difficulties that are associated with this global change, DEA believes that the 30-day deadline will allow sufficient flexibility under the circumstances, because the filing of a request for a hearing is a routine action. Since this final rule is not making any change in the current 30-day deadline, there is no reason to consider "staying" the effective date of this regulation.

Conclusion

In sum, DEA has reviewed all comments extensively and has taken them in full consideration when drafting these regulations. Accordingly, DEA is promulgating these regulations as written, with the exception of the 15-day period to request a hearing, as they create reasonable obligations which promote administrative efficiency while maintaining the due process rights of registrants.

Regulatory Analyses

Introduction

DEA received, and closely reviewed, all four comments that were submitted regarding this rulemaking. None of the comments raised issues that would require amendment of the analysis contained in the NPRM, with the exception of maintaining the 30-day deadline to request a hearing. Thus, the regulatory analyses here closely mirror the data and conclusions contained in the NPRM, and are repeated here for convenience.

Executive Orders 12866, and 13563 (Regulatory Planning and Review and Improving Regulation and Regulatory Review)

This rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866 classifies a "significant regulatory action," requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O. The Office of Management and Budget (OMB) has determined that this rule is not a "significant regulatory action" under E.O. 12866, section 3(f), and it has not been reviewed by OMB.

DEA estimates that there are both costs and cost savings associated with this rule. The provisions of this rule apply only to the small minority of applicants and registrants who are issued an OTSC. Therefore, a very small

minority of registrants will be economically impacted. From 2016 to 2018, there were on average 81 OTSCs issued annually. These 81 OTSCs fall into one of three categories: (1) an average of 29 cases in which the registrant/applicant surrendered and/or withdrew their application, thus mooting the case; (2) an average of 11 cases in which the registrant/applicant properly requested a hearing; and (3) the remaining 41 registrants/applicants per year who failed to timely file a request for a hearing and were deemed to have waived their right to a hearing and who would be in default under this rule. The 11 registrants/applicants per year who properly requested a hearing are estimated to incur costs while the registrants/applicants in the remaining two categories do not.

This rulemaking requires that a registrant/applicant must file an answer responding to every factual allegation in the OTSC. The average of 29 cases in which the registrant/applicant surrenders or withdraws their application, thus mooting the case, will not result in the registrant/applicant filing an answer to the OTSC. Therefore, these registrants/applicants will not incur any costs. The average of 11 cases per year where a registrant/applicant requests a hearing may incur a cost associated with answering the factual allegation(s) of the OTSC. To estimate the cost of this change, DEA estimates that, on average, it will take five hours for a registrant's/applicant's attorney to review the OTSC and prepare an answer to all allegations. Thus, the total estimated cost of this change is \$36,190 per year.9

The remaining 41 cases, where there was neither a registration surrendered nor a hearing conducted, would be differently impacted by this rule. This rule provides that where a party defaults, the factual allegations of the OTSC are deemed admitted. For these 41 cases, where there was registrant/ applicant inaction, the registrant's/ applicant's cost of inaction is the same under current rules. There is no additional cost to registrants/applicants. This rule provides that a default may only be set aside upon a party establishing good cause to excuse its default. DEA has no basis to estimate the number of affected parties who may seek to establish good cause to set aside

a default and any costs associated with such activities. However, under *Kamir Garces Mejias*, 72 FR 54931 (2007), a party seeking to be excused from an Administrative Law Judge (ALJ) order terminating a proceeding for failing to comply with the ALJ's orders is required to show good cause to excuse its default. Thus, because this requirement of the rule simply codifies case law, it imposes no additional cost to registrants.

Finally, this rulemaking will result in cost savings for DEA by streamlining the Administrator's review process using the default determination. The rule provides that when a registrant/ applicant is deemed to be in default, DEA may then file a request for final agency action along with a record to support its request with the Administrator who may enter a default. This record should include, for instance, documents demonstrating adequate service of process and, where a party held to be in default asserted that the default should be excused, any pleadings filed by both the parties addressing this issue. A registrant/ applicant who has defaulted under this rule is deemed to admit all of the factual allegations in the OTSC.

In contrast, under the current rules, in cases where the registrant/applicant waives their right to a hearing, DEA counsel must provide the Administrator with a much more voluminous record, including evidence to support each factual allegation which DEA seeks to establish. Because DEA's current rules do not provide that a registrant's/ applicant's waiver of their right to a hearing constitutes an admission of the factual allegations of the OTSC, both the preparation of the record by DEA counsel for submission to the Administrator and the process of reviewing the record and drafting the Administrator's final order require a significant investment of agency resources. The changes implemented here would thus save these resources, which can then be devoted to other pending matters in which the registrant/ applicant does contest the allegations in the OTSC, and reduce the time it takes for the Administrator's final order to issue in those cases where registrants/ applicants choose not to challenge the proceeding or fail to properly participate in the proceeding.

To estimate the cost savings of this rule, DEA first estimates the amount of time and resources that would be saved for cases that would be resolved via entry of a default. The complexity of a given case would impact both how much time it would take to prepare the request for final agency action and for the Administrator's Office to draft the

final order based on that final agency action request, which cumulatively would represent the amount of resources saved in a given case. For a case based solely on allegations related to a lack of state authority, or an exclusion from federal health care programs, the gathering of the evidence, including declarations, and preparation of the final agency action motion take, on average, approximately 10-15 hours. For cases with substantive allegations (most commonly, improper prescribing or filling of prescriptions), the preparation of the final agency action materials is considerably longerapproximately 30–40 hours per case. It is estimated that of the cases in which there was neither a hearing request nor a registration surrender, roughly 30-40 percent are No State License (NSL) cases, and 60-70 percent of cases would be considered other non-NSL cases. For the purpose of this analysis, DEA estimates that of the 41 cases this rule would impact on average each year, 65 percent would be considered non-NSL cases and take 35 hours per case to prepare a final agency action, while 35 percent would be considered NSL cases and take 13 hours per case to prepare a final agency action. Applying the loaded wage ¹⁰ for GS-15 Step 5 employees, ¹¹ DEA estimates the cost savings of this rule for the time it would take to prepare the final agency action request is around \$134,065 per year. 12

Additionally, there are cost savings from the time it would take the Administrator's Office to draft the final order based on that final agency action request. The cost savings for the Administrator's review process would be the most significant for all substantive cases that would be subject to the rule. The Administrator's review process consists of the time to review

 $^{^9}$ Hourly rate using Laffey Matrix for lawyers with 8–10 years of experience from 6/1/18 to 5/31/19 is \$658 per hour. Total Cost = (\$658 \times 5 \times 11). While it is possible the fees incurred for legal review and to answer the allegations would be offset by a reduction in fees later in the process. This is a new requirement and DEA conservatively estimates this requirement as a new cost.

¹⁰ The loaded wage includes the average benefits for employees in the government. Therefore, the loaded wage is the estimated cost of employment to the employer rather than the compensation to the employee.

¹¹ Hourly rate for GS-15 Step 5 employees in the Washington, DC region is \$74.86. 2019 General Schedule Locality Pay Tables for the Washington-Baltimore-Arlington area, Office of Personnel Management, https://www.opm.gov/policy-dataoversight/pay-leave/salaries-wages/salary-tables/ pdf/2019/DCB_h.pdf. Average benefits for state government employees is 37.5% of total compensation. Employer Costs for Employee Compensation—December 2018, Bureau of Labor Statistics, https://www.bls.gov/news.release/ archives/ecec_03192019.pdf. The 37.5% of total compensation equates to 60% (37.5%/62.5%) load on wages and salaries. The loaded hourly rate is \$119.78 (\$74.86 \times 1.6). The ECEC does not provide figures for Federal Government employees; therefore, figures for state employees are used as

 $^{^{12}}$ (\$119.78 \times 41 \times 65 % \times 35) + (\$119.78 \times 41 \times 35 % \times 13).

the final agency action request, evaluate the evidence submitted by DEA counsel, draft a decision, and the time the Administrator must spend reviewing the proposed decision. On average, there are four substantive cases per year that would be subject to the rule. Currently, the estimated time it takes for the substantive cases is 30 days or 240 hours per case. With the rule promulgated, the estimated time it will take for these substantive cases will be between one day and two weeks depending on the complexity of the case. For the purpose of this analysis, DEA estimates it will take seven days or 56 hours per case. Using the loaded hourly wage of a GS-15 Step 5 employee, the estimated cost savings for substantive cases is \$88,155 per year. 13 There is also cost savings for nonsubstantive cases, but DEA believes this cost savings to be minimal for the Administrator's review process. Also, while there is a difference in the legal definition of "deemed to have waived" versus "deemed to be in default," there is no enhancement of potential savings. The Administrator will continue to issue the final order based on the same set of circumstances regarding the OTSC and the default determination, versus the current "deemed to have waived" determination with the additional voluminous record provided. Therefore, the cost savings due to the Administrator's review process is estimated to be around \$88.155 per year.

In sum, there are both costs and cost savings associated with this rule. DEA has no basis to estimate the additional litigation costs for registrants who are "deemed to be in default" as a result of their failure to comply with the requirements of the rule as compared to registrants who are "deemed to have waived" under the prior regulations, but believes this additional litigation cost to be minimal due to the small number of these cases occurring each year. The total cost to registrants due to the requirement that a registrant/applicant must file an answer to an OTSC is \$36,190 per year. This rule has an estimated cost savings of \$222,220 (\$134,065 + \$88,155) per year for DEA by streamlining the Administrator's review process using the default determination. The estimated net cost savings of this rule is \$186,030 (\$222,220 – \$36,190) per year.

Executive Order 12988 (Civil Justice Reform)

This rule meets the applicable standards set forth in sections 3(a) and

3(b)(2) of E.O. 12988, Civil Justice Reform, to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132 (Federalism)

This rule 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. Therefore, in accordance with E.O. 13132, the DEA has determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism assessment.

Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) requirements do not apply to "the collection of information . . . during the conduct of . . . an administrative action or investigation involving an agency against specific individuals or entities." ¹⁴ These rules involve the collection of information pursuant to administrative actions, orders to show cause specifically, against specific registrants. Thus, this rulemaking is exempted from the requirements under PRA.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–12) (RFA), has reviewed this rule and by approving it certifies that this rule will not have a significant economic impact on a substantial number of small entities.

In accordance with the RFA, DEA evaluated the impact of this rule on small entities. This rule adds provisions allowing the entry of a default where a party served with an OTSC fails to request a hearing, fails to file an answer to the OTSC, or otherwise fails to defend against the OTSC. *Cf.* Fed. R. Civ. P. 55(a). The rule provides that where a party defaults, the factual

allegations of the OTSC are deemed admitted. Further, the rule removes the current provisions allowing a recipient of an OTSC to file a written statement while waiving their right to an administrative hearing.

As all DEA registrants are subject to the amended administrative enforcement procedures, the rule could potentially affect any person holding or planning to hold a DEA registration to handle controlled substances and those manufactures, distributors, importers, and exporters of list I chemicals. As of March 2019, there were approximately 1.8 million DEA registrations for controlled substances and list I chemicals. Registrants include individual practitioners (such as physicians, dentists, mid-level practitioners, etc.), business entities (such as offices of physicians, pharmacies, hospitals, pharmaceutical manufacturers, distributors, importers, exporters, etc.), and governmental or tribal agencies that handle controlled substances or list I chemicals.

In practice, a very small minority of DEA registrants are served with OTSCs in connection with the denial or cancellation of registration, and thus a very small minority of DEA registrants would be impacted by the rule. Over the three-year period 2016-2018, there was an average of 81 OTSCs served per vear. These 81 OTSCs fall into one of three categories: (1) an average of 29 cases in which the registrant/applicant surrendered the registration and/or withdrew their application, thus mooting the case; (2) an average of 11 cases in which the registrant/applicant properly requested a hearing; and (3) the remaining 41 registrants/applicants per year who failed to timely file a request for a hearing and were deemed to have waived their right to a hearing (and would be in default under this rule). The 11 registrants per year who properly requested a hearing are estimated to incur costs while the registrants in the remaining two categories do not.

This rulemaking requires that a registrant/applicant must file an answer responding to every allegation in the OTSC. The average of 29 cases in which the registrant/applicant surrenders or withdraws their application, thus mooting the case, would not result in the registrant/applicant filing an answer to the allegations in the OTSC. Therefore, these registrants/applicants would not incur any costs. The average of 11 cases per year where a registrant/ applicant requests a hearing may incur a cost associated with answering the allegation(s) of the OTSC. To estimate the cost of this change, DEA estimates

 $^{^{13}(4 \}times 240 \times \$119.78) - (4 \times 56 \times \$119.78) = \$88,155.$

^{14 44} U.S.C. 3501 et. seq.

that, on average, it will take five hours for a registrant/applicant's attorney to review the OTSC and prepare an answer to all allegations, or an average of \$3,290 per registrant.¹⁵

The remaining 41 cases, where there was neither a registration surrendered nor a hearing conducted, would be differently impacted by this rule. This rulemaking provides that where a party defaults, the factual allegations of the OTSC are deemed admitted. This rulemaking also provides that a default may only be set aside upon a party establishing good cause to excuse its default. DEA has no basis to estimate the number of affected parties who will seek to establish good cause to set aside a default and any costs associated with such activities. However, under Kamir Garces Mejias, a party seeking to be excused from an ALJ order terminating a proceeding for failing to comply with the ALJ's orders is required to show

good cause to excuse its default. 72 FR 54931 (2007). Thus, because this requirement of the rule simply codifies case law, it imposes no additional cost to registrants.

In summary, it is estimated that there will be an average of 11 cases per year, in which the registrant/applicant properly requests a hearing and will incur an economic impact of \$3,290. Because the subject of the 11 cases can be an individual or entity (i.e., offices of physicians, pharmacies, hospitals, pharmaceutical manufacturers, distributors, importers, exporters, governmental or tribal agencies, etc.), DEA compared the estimated cost of \$3,290 to the average revenue of the smallest entities for some representative North American Industry Classification System (NAICS) codes for DEA registrants using data from U.S. Census Bureau, Statistics of U.S. Businesses (SUSB).

For example, there are a total of 174,901 entities in NAICS code, 621111-Office of Physicians (Except Mental Health Specialists). Of the 174,901 total entities, DEA estimates that 97.6% are small entities. DEA compared the estimated cost of \$3,290 to the revenue of the smallest of small entities, those with 0-4 employees. There are 95,494 entities in the 0-4 employee category with a combined total annual revenue of \$42,823,012,000, or an average of \$448,000 per entity (rounded to nearest thousand). 16 The estimated cost of \$3,290 is 0.73% the average annual revenue of \$448,000. The same analysis was conducted for each representative NAICS code. The cost as percent of average revenue for the smallest of small entities ranges from 0.24% to 1.30%. The table below summarizes the analysis and results.

			Estimated	Smallest employment size category analysis				
NAICS code	NAICS code-description	Total number of entities	number of small entities	Employment size (number of employees)	Number of firms	Estimated receipts (\$000)	Average revenue per firm (\$000)	Cost as % of revenue
325412	Pharmaceutical Preparation Manufacturing	930	863	0–4	297	N/A	N/A	N/A
424210	Drugs and Druggists' Sundries Merchant Wholesalers.	6,618	6,348	0–4	3,628	4,962,687	1,368	0.24
446110	Pharmacies and Drug Stores	18,852	18,481	0–4	6,351	6,803,003	1,071	0.31
541940	Veterinary Services	27,708	27,032	0–4	8,878	2,594,724	292	1.13
621111	Offices of Physicians (except Mental Health Specialists).	174,901	170,634	0–4	95,494	42,823,012	448	0.73
621112	Offices of Physicians, Mental Health Specialists.	10,876	10,611	0–4	8,977	2,279,458	254	1.30
621210	Offices of Dentists	125,151	122,097	0–4	50,711	16,801,830	331	0.99
621320	Offices of Optometrists	19,731	19,250	0–4	10,913	2,946,400	270	1.22
621391	Offices of Podiatrists	8,122	7,924	0–4	5,284	1,529,293	289	1.14

In conclusion, this rulemaking will have an estimated cost of \$3,290 on an average of 11 small entities per year. The \$3,290 is estimated to represent 0.24%–1.30% of annual revenue for the smallest of small entities, entities with 0–4 employees. Therefore, DEA estimates this rulemaking will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

DEA has determined that this action would not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any 1 year." ¹⁷ Therefore, neither a Small Government

Agency Plan nor any other action is required under the UMRA.

Congressional Review Act

This rulemaking is not a "major rule" under the Congressional Review Act, 5 U.S.C. 801 *et seq.*¹⁸ DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Exports, Imports, Security measures.

21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, Exports, Imports.

June 2015. SUSB annual or static data include number of firms, number of establishments, employment, and annual payroll for most U.S. business establishments. The data are tabulated by geographic area, industry, and employment size of the enterprise. The industry classification is based

21 CFR Part 1316

Administrative practice and procedure, Authority delegations (Government agencies), Drug traffic control, Research, Seizures, and forfeitures.

For the reasons stated in the preamble, DEA amends 21 CFR parts 1301, 1309, and 1316 as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965 unless otherwise noted.

 $^{^{15}}$ Hourly rate using Laffey Matrix for lawyers with 8–10 years of experience from 6/1/18 to 5/31/19 is \$658 per hour. \$658 \times 5 = \$3,290.

¹⁶ Data for NAICS codes are based on the 2012 SUSB Annual Datasets by Establishment Industry,

on 2012 North American Industry Classification System (NAICS) codes.

^{17 2} U.S.C. 1532(a).

¹⁸ 5 U.S.C. 804(2)(A)–(C), 804(3); see 5 U.S.C. 551(4).

■ 2. In § 1301.37, revise paragraph (d) to read as follows:

§ 1301.37 Order to show cause.

* * * * *

(d)(1) When to File: Hearing Request. A party that wishes to request a hearing in response to an order to show cause must file with the Office of the Administrative Law Judges and serve on DEA such request no later than 30 days following the date of receipt of the order to show cause. Service of the request on DEA shall be accomplished by sending it to the address, or email address, provided in the order to show cause.

(2) When to File: Answer. A party requesting a hearing shall also file with the Office of the Administrative Law Judges and serve on DEA an answer to the order to show cause no later than 30 days following the date of receipt of the order to show cause. A party shall also serve its answer on DEA at the address, or the email address, provided in the order to show cause. The presiding officer may, upon a showing of good cause by the party, consider an answer that has been filed out of time.

- (3) Contents of Answer; Effect of Failure to Deny. For each factual allegation in the order to show cause, the answer shall specifically admit, deny, or state that the party does not have and is unable to obtain sufficient information to admit or deny the allegation. When a party intends in good faith to deny only a part of an allegation, the party shall specify so much of it as is true and shall deny only the remainder. A statement of a lack of information shall have the effect of a denial. Any factual allegation not denied shall be deemed admitted.
- (4) Amendments. Prior to the issuance of the prehearing ruling, a party may as a matter of right amend its answer one time. Subsequent to the issuance of the prehearing ruling, a party may amend its answer only with leave of the presiding officer. Leave shall be freely granted when justice so requires.
- 3. Amend § 1301.43, by revising the section heading and paragraphs (c), (d), and (e), and by adding paragraph (f) to read as follows:

§ 1301.43 Request for hearing or appearance; waiver; default.

* * * * *

(c)(1) Any person entitled to a hearing pursuant to § 1301.32 or 1301.34 through 36 who fails to file a timely request for a hearing shall be deemed to have waived their right to a hearing and to be in default, unless the registrant/applicant establishes good cause for failing to file a timely hearing request.

Any person who has failed to timely request a hearing under paragraph (a) of this section may seek to be excused from the default by filing a motion with the Office of Administrative Law Judges establishing good cause to excuse the default no later than 45 days after the date of receipt of the order to show cause. Thereafter, any person who has failed to timely request a hearing under paragraph (a) of this section and seeks to be excused from the default shall file such motion with the Office of the Administrator, which shall have exclusive authority to rule on the motion.

(2) Any person who has requested a hearing pursuant to this section but who fails to timely file an answer and who fails to demonstrate good cause for failing to timely file an answer, shall be deemed to have waived their right to a hearing and to be in default. Upon motion of DEA, the presiding officer shall then enter an order terminating the proceeding.

(3) In the event DEA fails to prosecute or a person who has requested a hearing fails to plead (including by failing to file an answer) or otherwise defend, said party shall be deemed to be in default and the opposing party may move to terminate the proceeding. Upon such motion, the presiding officer shall then enter an order terminating the proceeding, absent a showing of good cause by the party deemed to be in default. Upon termination of the proceeding by the presiding officer, a party may seek relief only by filing a motion establishing good cause to excuse its default with the Office of the Administrator.

(d) If any person entitled to participate in a hearing pursuant to this section fails to file a notice of appearance either as part of a hearing request or separately, or if such person so files and fails to appear at the hearing, such person shall be deemed to have waived their opportunity to participate in the hearing, unless such person shows good cause for such failure.

(e) A default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing and an admission of the factual allegations of the order to show cause.

(f)(1) In the event that a registrant/ applicant is deemed to be in default pursuant to paragraph (c)(1) of this section, and has not established good cause to be excused from the default, or the presiding officer has issued an order terminating the proceeding pursuant to paragraphs (c)(2) or (c)(3) of this section, DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to § 1316.67 of this chapter.

(2) In the event that DEA is deemed to be in default and the presiding officer has issued an order terminating the proceeding pursuant to paragraph (c)(3) of this section, the presiding officer shall transmit the record to the Administrator for his consideration no later than five business days after the date of issuance of the order. Upon termination of the proceeding by the presiding officer, DEA may seek relief only by filing a motion with the Office of the Administrator establishing good cause to excuse its default.

(3) A party held to be in default may move to set aside a default final order issued by the Administrator by filing a motion no later than 30 days from the date of issuance by the Administrator of a default final order. Any such motion shall be granted only upon a showing of good cause to excuse the default.

PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF LIST I CHEMICALS

■ 4. The authority citation for part 1309 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 823, 824, 830, 871(b), 875, 877, 886a, 952, 953, 957, 958.

■ 5. In § 1309.46, revise paragraph (d) to read as follows:

§ 1309.46 Order to Show Cause.

* * * * *

(d)(1) When to File: Hearing Request. A party that wishes to request a hearing in response to an order to show cause must file with the Office of the Administrative Law Judges and serve on DEA such request no later than 30 days following the date of receipt of the order to show cause. Service of the request on DEA shall be accomplished by sending it to the address, or email address, provided in the order to show cause.

(2) When to File: Answer. A party requesting a hearing shall also file with the Office of the Administrative Law Judges and serve on DEA an answer to the order to show cause no later than 30 days following the date of receipt of the order to show cause. A party shall also serve its answer on DEA at the address, or email address, provided in the order to show cause. The presiding officer may, upon a showing of good cause by the party, consider an answer that has been filed out of time.

(3) Contents of Answer; Effect of Failure to Deny. For each factual

allegation in the order to show cause, the answer shall specifically admit, deny, or state that the party does not have, and is unable to obtain, sufficient information to admit or deny the allegation. When a party intends in good faith to deny only a part of an allegation, the party shall specify so much of it as is true and shall deny only the remainder. A statement of a lack of information shall have the effect of a denial. Any factual allegation not denied shall be deemed admitted.

- (4) Amendments. Prior to the issuance of the prehearing ruling, a party may as a matter of right amend its answer one time. Subsequent to the issuance of the prehearing ruling, a party may amend its answer only with leave of the presiding officer. Leave shall be freely granted when justice so requires.
- 6. Amend § 1309.53, by revising the section heading and paragraphs (b), (c), and (d), and adding paragraph (e) to read as follows:

§ 1309.53 Request for hearing or appearance; waiver; default.

* * * * *

- (b)(1) Any person entitled to a hearing pursuant to § 1309.42 or 1309.43 who fails to file a timely request for a hearing, shall be deemed to have waived their right to a hearing and to be in default, unless the registrant/applicant establishes good cause for failing to file a timely hearing request. Any person who has failed to timely request a hearing under paragraph (a) may seek to be excused from the default by filing a motion with the Office of Administrative Law Judges establishing good cause to excuse the default no later than 45 days after the date of receipt of the order to show cause. Thereafter, any person who has failed to timely request a hearing under paragraph (a) and seeks to be excused from the default, shall file such motion with the Office of the Administrator, which shall have exclusive authority to rule on the motion.
- (2) Any person who has requested a hearing pursuant to this section but who fails to timely file an answer and who fails to demonstrate good cause for failing to timely file an answer, shall be deemed to have waived their right to a hearing and to be in default. Upon motion of DEA, the presiding officer shall then enter an order terminating the proceeding.
- (3) In the event DEA fails to prosecute or a person who has requested a hearing fails to plead (including by failing to file an answer) or otherwise defend, said party shall be deemed to be in default and the opposing party may move to

- terminate the proceeding. Upon such motion, the presiding officer shall then enter an order terminating the proceeding, absent a showing of good cause by the party deemed to be in default. Upon termination of the proceeding by the presiding officer, a party may seek relief only by filing a motion establishing good cause to excuse its default with the Office of the Administrator.
- (c) If any person entitled to participate in a hearing pursuant to this section fails to file a notice of appearance either as part of a hearing request or separately, or if such person so files and fails to appear at the hearing, such person shall be deemed to have waived their opportunity to participate in the hearing, unless such person shows good cause for such failure.
- (d) A default, unless excused, shall be deemed to constitute a waiver of the applicant's/registrant's right to a hearing and an admission of the factual allegations of the order to show cause.
- (e)(1) In the event that a registrant/ applicant is deemed to be in default pursuant to paragraph (b)(1) of this section and has not established good cause to be excused from the default, or the presiding officer has issued an order termination the proceeding pursuant to paragraphs (b)(2) or (b)(3) of this section, DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to § 1316.67 of this chapter.
- (2) In the event that DEA is deemed to be in default and the presiding officer has issued an order terminating the proceeding pursuant to paragraph (b)(3) of this section, the presiding officer shall transmit the record to the Administrator for his consideration no later than five business days after the date of issuance of the order. Upon termination of the proceeding by the presiding officer, DEA may seek relief only by filing a motion with the Office of the Administrator establishing good cause to excuse its default.
- (3) A party held to be in default may move to set aside a default final order issued by the Administrator by filing a motion no later than 30 days from the date of issuance by the Administrator of a default final order. Any such motion shall be granted only upon a showing of good cause to excuse the default.

PART 1316—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

■ 7. The authority citation for part 1316, subpart D, continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 875, 958(d), 965.

■ 8. Revise § 1316.47 to read as follows:

§ 1316.47 Request for hearing; answer.

(a) Any person entitled to a hearing and desiring a hearing shall, within the period permitted for filing, file a request for a hearing that complies with the following format (see the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address): (Date)

Drug Enforcement Administration, Attn: Hearing Clerk/OALJ

(Mailing Address)

Subject: Request for Hearing

Dear Sir:

The undersigned ______ (Name of the Person) hereby requests a hearing in the matter of: ______ (Identification of the proceeding).

(State with particularity the interest of the person in the proceeding.)

All notices to be sent pursuant to the proceeding should be addressed to:

_

- (b) A party shall file an answer as required under §§ 1301.37(d) or 1309.46(d) of this chapter, as applicable. The presiding officer, upon request and a showing of good cause, may grant a reasonable extension of the time allowed for filing the answer.
- 9. Revise the first sentence of § 1316.49 to read as follows:

§ 1316.49 Waiver of hearing.

In proceedings other than those conducted under part 1301 or part 1309 of this chapter, any person entitled to a hearing may, within the period permitted for filing a request for hearing or notice of appearance, file with the Administrator a waiver of an opportunity for a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on November 3, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2022-24425 Filed 11-10-22; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Part 537 RIN 3141-AA58

Management Contracts

AGENCY: National Indian Gaming

Commission. **ACTION:** Final rule.

SUMMARY: The National Indian Gaming Commission (NIGC or Commission) issued a proposed rule revising its management contract regulations. The Indian Gaming Regulatory Act (IGRA) provides that an Indian tribe may enter into a management contract for the operation of Class II or Class III gaming activity if such contract has been submitted to and approved by the NIGC Chairman. Collateral agreements to a management contract are also subject to the Chairman's approval. This final rule makes background investigations required of all persons who have 10 percent or more direct or indirect financial interest in a management contract, of all entities with 10 percent or more financial interest in a management contract, of any other person or entity with a direct or indirect financial interest in a management contract otherwise designated by the Commission, and authorizes the Chairman, either by request or unilaterally, to exercise discretion to reduce the scope of the information to be furnished and background investigation to be conducted for certain entities.

DATES: This rule is effective December 14, 2022.

FOR FURTHER INFORMATION CONTACT: Michael Hoenig, 1849 C Street NW, Mail Stop #1621, Washington, DC 20240. Telephone: 202–632–7003.

SUPPLEMENTARY INFORMATION:

I. Background

The Indian Gaming Regulatory Act (IGRA or Act), Public Law 100-497, 25 U.S.C. 2701 *et seq.*, was signed into law on October 17, 1988. The Act establishes the NIGC and sets out a comprehensive framework for the regulation of gaming on Indian lands. On January 22, 1993, the NIGC published a final rule in the Federal Register called Background Investigations for Person or Entities with a Financial Interest in a Management Contract (58 FR 5831). The rule added a new part to the Commission's regulations implementing the mandates of the Indian Gaming Regulatory Act of 1988 by establishing the requirements and procedures for the approval of management contracts concerning Indian gaming operations and the conduct of related background investigations. The Commission has substantively amended them numerous times, most recently in 2012 (August 9, 2012; 77 FR 47514). On December 2, 2021, the NIGC published a notice of proposed rulemaking in the Federal Register called Background Investigations for Persons or Entities With a Financial Interest in or Having a Management Responsibility for a Management Contract (86 FR 68446).

II. Development of the Rule

On June 9, 2021, the Commission issued a Dear Tribal Leader Letter announcing the beginning of tribal consultations on 25 CFR 537.1(a)(3), among other regulations. On July 12, 2021, the Commission issued a second Dear Tribal Leader Letter announcing the dates of virtual consultations and seeking written comments on the proposed changes to part 537. On July 27, 2021, and July 28, 2021, the Commission held virtual consultations and accepted comments from Tribes on those changes.

Upon reviewing the comments received during the consultation period from July 12—August 12, 2021, the Commission published a Notice of Proposed Rulemaking (NPRM) on December 2, 2021 (86 FR 68446). The NPRM invited interested parties to participate in the rulemaking process by submitting comments and any supporting data to the NIGC by January 3, 2022. The consultation and the written comments have proven invaluable to the Commission in making amendments to the Management Contract regulations.

III. Review of Public Comments

Comment: One commenter suggested that the term "Chairman" be changed to "Chair" throughout the regulation.

Response: The Commission agrees with the recommendation and has made that change.

Comment: One commenter suggested that the term "indirect financial interest" was too vague and possibly too broad and should be deleted or defined.

Response: Under IGRA, the NIGC has broad authority to ensure compliance with IGRA. Individuals or entities can have an "indirect financial interest" in innumerable ways. Any effort to define this term to specific types of relationships would improperly and unnecessarily limit the Commission's authority to regulate financial interests in Indian gaming.

Comment: Several commenters suggest that the NIGC include information as to how and when the Commission will notify a TGRA of a unilateral decision by the Chair to reduce the scope of required information or, alternatively, what would need to be included in a request submitted by TGRAs for the same.

Response: The Commission appreciates the comments and clarifies that background investigations and suitability determinations discussed in this part pertain to management companies wishing to enter into an agreement with a tribe, not the tribe itself. As such, a request for a reduced scope background investigation would typically be made by, and granted to, a management company, individual or entity with management responsibility for the contract, or individual or entity with a direct or indirect financial interest. If a tribe or wholly owned tribal entity is proposing to manage another Tribe's gaming operation, they may request a reduced background investigation or the Chair may elect to perform one unilaterally. In either case, the NIGC will notify the requester of a decision. As to how to make a request, the Commission responds that it will set forth any process in a bulletin. If a potential management company has questions as to how to request a reduced scope background investigation prior to the issuance of that bulletin, the Commission invites them to contact the NIGC for further information.

Comment: Another commenter supports the change to clarify the reduced scope background investigation, but suggests the NIGC add examples of "approaches the Chair may take to reduce the scope of information to be furnished. The commenter included suggested language to include

in the regulation, including accepting "substantively current background information submitted previously to the Commission or other jurisdictions and providing reciprocity for background investigation results to reduce the burden of submitting duplicative information and reduce delay in background investigations."

Response: The Commission appreciates the commenter's support for the changes to clarify the reduced scope background investigation, and agrees that the examples suggested are a reasonable and sensible way to reduce the scope of the investigation. Ultimately, though, the Commission declines to include the suggested language. The scope of the background investigation, though reduced, is still at the discretion of the Chair, who must ultimately make the suitability determination for all entities and individuals backgrounded. The Commission does not intend through this amendment to prescribe what information the Chair must or may require as part of a reduced scope investigation.

Comment: One commenter suggested that the NIGC consider adding a standard for when the Chair exercises his or her discretion to approve a request for a reduced background investigation, *e.g.* what constitutes a "national bank" and to provide additional detail regarding what supporting documents tribes would be required to submit as well as timelines associated with such requests. Response: The Commission declines to define "National Bank" or "institutional investor" in its regulations, as these are terms commonly understood in the Banking and Finance industries. A National Bank is widely understood to mean a Commercial Bank formed under the National Bank Act, 12 U.S.C. 38, chartered by the Comptroller of the Currency, and a member of the Federal Deposit Insurance Company. The term "institutional investor" is defined by and must be registered with, the Securities and Exchange Commission.

Comment: One commenter objected to the NIGC changing its regulation to initially require background checks and suitability determination on entities and individuals that have 10 percent or more direct or indirect financial interest in a management contract. The Commenter believes that imposing a 10 percent interest threshold is "an arbitrary approach that will encourage bad actors' to structure their deals below the 10 percent threshold to avoid NIGC scrutiny. The Commenter further asserts that the change will improve efficiency at "the expense of tribes who

rely on the NIGC to keep 'bad actors' out of Indian gaming and that the amendment "conflicts with the requirements of the IGRA."

Response: The Commission thanks the Commenter for its input on this topic. It has determined to finalize the Change, however, and responds that the change will not negatively impact the agency's ability to protect the interests of Tribes. At the outset, it is important to note that the NIGC is not changing the requirement to submit any individual or entity that has management responsibility for the contract. Accordingly, the NIGC will still require background investigations and suitability determinations for all individuals and entities that may have any decision-making authority or influence over the contract or the Tribe's gaming operation

Rather, the purpose of the change is to reduce the time and expense of background investigations by no longer requiring the initial submission of those with minor financial interests in, but no control over, the management contract or the gaming operation. Moreover, the regulation includes a provision requiring a background investigation and suitability determination for "any other person or entity with a direct or indirect financial interest in a management contract otherwise designated by the Commission." When a management contract is submitted, the NIGC's background investigators ensure that the list that was submitted is accurate. As part of that review, they will ask for a full list of all the entities and individuals involved in, and with a financial interest in, the contract, even if not all of those entities and individuals will be subject to a background investigation. If, however, investigators identify an entity or individual that should be subject to further review, the Commission may order such pursuant to § 537.1(a)(3). For these reasons, the Commission does not believe the amendment creates any additional risk to Tribes, does not permit a bad actor to structure its management contract in a way that allows them to escape review from the NIGC, and meets IGRA's purpose of "shielding tribes from organized crime and other corrupting influences.'

Regulatory Matters

Regulatory Flexibility Act

The proposed rule will not have a significant impact on a substantial number of small entities as defined under the Regulatory Flexibility Act, 5 U.S.C. 601, et seq. Moreover, Indian Tribes are not considered to be small

entities for the purposes of the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act

The proposed rule is not a major rule under 5 U.S.C. 804(2), the Small **Business Regulatory Enforcement** Fairness Act. The rule does not have an effect on the economy of \$100 million or more. The rule will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, local government agencies, or geographic regions, nor will the proposed rule have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of the enterprises, to compete with foreign based enterprises.

Unfunded Mandate Reform Act

The Commission, as an independent regulatory agency, is exempt from compliance with the Unfunded Mandates Reform Act, 2 U.S.C. 1502(1); 2 U.S.C. 658(1).

Takings

In accordance with Executive Order 12630, the Commission has determined that the proposed rule does not have significant takings implications. A takings implication assessment is not required.

Civil Justice Reform

In accordance with Executive Order 12988, the Commission has determined that the rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

National Environmental Policy Act

The Commission has determined that the rule does not constitute a major federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321, et seq.

Paperwork Reduction Act

The information collection requirements contained in this rule were previously approved by the Office of Management and Budget (OMB) as required by 44 U.S.C. 3501 *et seq.* and assigned OMB Control Number 3141–0007.

Tribal Consultation

The National Indian Gaming Commission is committed to fulfilling its tribal consultation obligations whether directed by statute or administrative action such as Executive Order (E.O.) 13175 (Consultation and Coordination with Indian Tribal Governments)—by adhering to the consultation framework described in its Consultation Policy published July 15, 2013. The NIGC's consultation policy specifies that it will consult with tribes on Commission Action with Tribal Implications, which is defined as: Any Commission regulation, rulemaking, policy, guidance, legislative proposal, or operational activity that may have a substantial direct effect on an Indian tribe on matters including, but not limited to, the ability of an Indian tribe to regulate its Indian gaming; an Indian Tribe's formal relationship with the Commission; or the consideration of the Commission's trust responsibilities to Indian tribes.

Pursuant to this policy, on June 9, 2021, the National Indian Gaming Commission sent a Notice of Consultation announcing that the Agency intended to consult on a number of topics, including proposed changes to the management contract process. On July 27, 2021, and July 28, 2021, the Commission held two virtual consultations on the proposed changes to the management contract process.

List of Subjects in 25 CFR Part 537

Gambling, Indian—lands, Indian tribal government, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Commission amends 25 CFR part 537 as follows:

PART 537—BACKGROUND INVESTIGATIONS FOR PERSONS OR ENTITIES WITH A FINANCIAL INTEREST IN, OR HAVING MANAGEMENT RESPONSIBILITY FOR, A MANAGEMENT CONTRACT

■ 1. The authority citation for part 537 continues to read:

Authority: 25 U.S.C. 81, 2706(b)(10), 2710(d)(9), 2711.

■ 2. Amend § 537.1 by revising paragraphs (a)(1) through (3) and adding paragraph (d) to read as follows:

§ 537.1 Applications for approval.

- (a) * * *
- (1) All persons who have 10 percent or more or indirect financial interest in a management contract;
- (2) All entities with 10 percent or more financial interest in a management contract; and
- (3) Any other person or entity with a direct or indirect financial interest in a management contract otherwise designated by the Commission.

* * * * *

- (d) For any of the following entities, or individuals associated with the following entities, the Chair may, upon request or unilaterally, exercise discretion to reduce the scope of the information to be furnished and background investigation to be conducted:
 - (1) Tribe as defined at 25 CFR 502.13;
 - (2) Wholly owned Tribal entity;
 - (3) National bank; or
- (4) Institutional investor that is federally regulated or is required to undergo a background investigation and licensure by a State or Tribe pursuant to a Tribal-State compact.

Edward Simermeyer,

Chairman.

Jean Hovland,

Vice Chair.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9967]

RIN 1545-BO92

Section 42, Low-Income Housing Credit Average Income Test Regulations; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to the final regulations (Treasury Decision 9967) published in the Federal Register on Wednesday, October 12, 2022. This correction includes final and temporary regulations setting forth guidance on the average income test for purposes of the low-income housing credit.

DATES: These corrections are effective on *November 14, 2022* and applicable on or after October 12, 2022.

FOR FURTHER INFORMATION CONTACT:

Concerning the regulations, Dillon Taylor at (202) 317–4137.

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9967) subject to this correction are issued under section 42 of the Internal Revenue Code.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

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

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

■ Par. 2. Section 1.42–19 is amended by revising the first sentence of paragraph (d)(1)(v) to read as follows:

§ 1.42-19 Average income test.

(d) * * *

(d) ^ ^ ^ (1) * * *

(v) * * * If one or more units lose low-income status or if there is a change in the imputed income limitation of some unit and if either event would cause a previously qualifying group of units to cease to be described in paragraph (b)(2)(ii) of this section, then the taxpayer may designate an imputed income limitation for a market-rate unit or may reduce the existing imputed income limitations of one or more other units in the project in order to restore compliance with the average income requirement. * * *

Oluwafunmilayo A. Taylor,

Branch Chief, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2022–24636 Filed 11–10–22; 8:45 am]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9967]

RIN 1545-BO92

Section 42, Low-Income Housing Credit Average Income Test Regulations; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations; correction.

SUMMARY: This document contains corrections to the final regulations (Treasury Decision 9967) published in the Federal Register on Wednesday, October 12, 2022. This correction includes final and temporary regulations setting forth guidance on the average income test for purposes of the low-income housing credit.

DATES: These corrections are effective on *November 14, 2022* and applicable on or after October 12, 2022.

FOR FURTHER INFORMATION CONTACT:

Concerning the regulations, Dillon Taylor at (202) 317–4137.

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9967) subject to this correction are issued under section 42 of the Internal Revenue

Correction of Publication

Accordingly, the final regulations (TD 9967) that are the subject of FR Doc. 2022–22070, appearing on page 61489 in the **Federal Register** on October 12, 2022, are corrected to read as follows:

- 1. On page 61489, in the third column, in the thirteenth line from the top of the column, the language "142(d)(6))" is corrected to read "142(d)(6)".
- 2. On page 61490, in the third column, in the fourth and fifth lines from the bottom of the column, the language "market rate" is corrected to read "market-rate".
- 3. On page 61492, in the first column, the last line from the bottom of the column, the language "IRS" is corrected to read "the IRS".
- 4. On page 61492, in the third column, in the last paragraph, the seventh line from the top of the paragraph, the language "appliable" is corrected to read "applicable".
- 5. On page 61494, in the second column, in the last paragraph, the twelfth line from the bottom, the language "42(c)(1)(c)(i)" is corrected to read "42(c)(1)(i)(C)".

 6. On page 61495, in the third
- 6. On page 61495, in the third column, in the first full paragraph, in the third line, the language "proposal rule" is corrected to read "proposed rule".
- 7. On page 61497, in the third column, in the third full paragraph, in the tenth line from the top of the paragraph, the language "makes" is corrected to read "make".

 8. On page 61498, in the second
- 8. On page 61498, in the second column, in the first full paragraph, in the second and ninth lines from the top of the paragraph, the language "IRS" is corrected to read "the IRS".
- 9. On page 61500, in the second column, under the caption "III. Regulatory Flexibility Act", in the first full paragraph, in the tenth line from the bottom of the paragraph, the language "test)" is corrected to read "test".
- 10. On page 61500, in the second column, under the caption "III. Regulatory Flexibility Act", in the

second full paragraph, the third line from the bottom of the paragraph, the language "(v)" is corrected to read "(vi)".

Oluwafunmilayo A. Taylor,

Branch Chief, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2022–24634 Filed 11–10–22; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2022-0826]

RIN 1625-AA09

Drawbridge Operation Regulation; Hackensack River, Jersey City, NJ

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily modifying the operating schedule that governs the PATH Bridge across the Hackensack River, mile 3.0, at Jersey City, New Jersey. This action is necessary to allow for an unexpected delay in material delivery related to COVID–19 pandemic. This temporary final rule is necessary to allow the bridge owner to complete the remaining replacements and repairs.

DATES: This temporary final rule is effective 12:01 a.m. on November 14, 2022, through 12:01 a.m. on March 23, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to https://www.regulations.gov. Type the docket number (USCG-2022-0806) in the "SEARCH" box and click "SEARCH". In the Document Type column, select "Supporting & Related Material".

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary final rule, call or email Judy Leung-Yee, Bridge Management Specialist, U.S. Coast Guard; telephone: 212–514–4336, email: Judy.K.Leung-Yee@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
OMB Office of Management and Budget
NPRM Notice of proposed rulemaking
Pub. Law Public Law
§ Section

U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable.

On March 24, 2022, the Coast Guard issued a General Deviation for 180 days which allowed the bridge owner to deviate from the current operating schedule in 33 CFR 117.732(b) to repair the bridge. This deviation letter can be found in this Docket as supporting documentation. Due to delays in procuring materials for replacement of the bridge control system the project ran past the allotted 180 days. The work cannot stop and needs to continue in order to bring the bridge back to normal operation. Therefore, there is lack of sufficient time to provide a reasonable comment period and then consider those comments before issuing the modification.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective in less than 30 days after publication in the **Federal Register**. For reasons presented above, delaying the effective date of this rule would be impracticable and contrary to the public interest given the need to complete repairs to the bridge which are already underway and preventing full operation.

III. Legal Authority and Need for the Rule

The Coast Guard is issuing this rule under authority 33 U.S.C. 499. The Coast Guard is modifying the operating schedule that governs the PATH Bridge across Hackensack River, mile 3.0, at Jersey City, New Jersey. The PATH Bridge is a vertical lift bridge offering mariners a vertical clearance of 40 feet at mean high water and 45 feet at mean low water in the closed position.

The existing drawbridge regulations are listed at 33 CFR 117.723(b). The Port Authority Trans-Hudson Corporation, the bridge owner, has requested this modification as additional time is

required to complete replacement of control system as described above.

The waterway is transited by seasonal recreational traffic as well as commercial vessels, largely tug and barge combinations. The 40-foot vertical clearance while the bridge is in the closed position offers the bulk of commercial traffic sufficient room to transit under the bridge. Coordination with known waterway users has indicated no objection to the proposed schedule of the draw. Vessels that can pass under the bridge without an opening may do so at all times. The bridge will be able to open for emergencies. There is no immediate alternate route for vessels unable to pass through the bridge when in the closed position.

IV. Discussion of the Rule

The Coast Guard is issuing this rule, which permits a temporary deviation from the operating schedule that governs the PATH Bridge across Hackensack River, mile 3.0, at Jersey City, New Jersey. The rule is necessary to accommodate the completion of replacement of control system. This rule allows the bridge to open on signal provided a minimum of twenty-four (24) hours advance notice is given, and need not open for the passage of vessel traffic on weekdays Monday through Friday from 6 a.m. to 10 a.m. and from 3 p.m. to 7 p.m. from November 6, 2022, to March 22, 2023.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the ability that vessels can still transit the bridge given advanced notice.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on

small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the bridge may be small entities, for the reasons stated in section V.A. above, this rule will not have a significant economic impact on any vessel owner or operator.

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Government

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, Rev.1, associated implementing instructions, and Environmental Planning Policy COMDTINST 5090.1 (series) which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f). The Coast Guard has determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule promulgates the operating regulations or procedures for drawbridges and is categorically excluded from further review, under paragraph L49, of Chapter 3, Table 3-1 of the U.S. Coast Guard **Environmental Planning** Implementation Procedures.

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

List of Subjects in 33 CFR Part 117

Bridges.

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

PART 117—DRAWBRIDGE OPERATION REGULATIONS

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

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

- 2. Amend § 117.723 as follows:
- a. Stay paragraph (b).

■ b. Add paragraph (l).
The addition reads as follows:

§ 117.723 Hackensack River.

(l) The draw of the PATH Bridge, mile 3.0, at Jersey City, shall open on signal provided at least a twenty-four (24) hour advance notice is provided by calling the U.S. Coast Guard Vessel Traffic Service (VTS) at 718–514–4088 or Port Authority Trans-Hudson, John Burkhard, at 201-410-4260 to coordinate a transit time that is mutually acceptable for commercial river users to pass under the bridge. The draw need not open for the passage of vessel traffic on weekdays Monday through Friday, except Federal holidays, from 6 a.m. to 10 a.m. and from 3 p.m. to 7 p.m.

Dated: November 2, 2022.

J.W. Mauger,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 2022–24706 Filed 11–10–22; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2022-0929] RIN 1625-AA87

Security Zones; Corpus Christi Ship Channel, Corpus Christi, TX

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary, 500-yard radius, moving security zone for a certain vessel carrying Certain Dangerous Cargoes (CDC) within the Corpus Christi Ship Channel and La Quinta Channel. The temporary security zone is needed to protect the vessels, the CDC cargo, and the surrounding waterway from terrorist acts, sabotage, or other subversive acts, accidents, or other events of a similar nature. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Corpus Christi or a designated representative.

DATES: This rule is effective from November 14, 2022, until November 17, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander Anthony

Garofalo, Sector Corpus Christi Waterways Management Division, U.S. Coast Guard; telephone 361–939–5130, email Anthony.M.Garofalo@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector Corpus
Christi
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. We must establish this security zone by November 14, 2022, to ensure security of this vessel and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because immediate action is needed to provide for the security of the vessel.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Sector Corpus Christi (COTP) has determined that potential hazards associated with the transit of the Motor Vessel (M/V) TENERGY when loaded will be a security concern within a 500-yard radius of the vessel. This rule is needed to provide for the safety and security of the vessels, their cargo, and surrounding waterway from terrorist acts, sabotage or other subversive acts, accidents, or other events of a similar nature while they are transiting within Corpus Christi, TX, from November 14, 2022, through November 17, 2022.

IV. Discussion of the Rule

The Coast Guard is establishing four 500-yard radius temporary moving security zones around M/V TENERGY. The zone for the vessel will be enforced from November 14, 2022, until November 17, 2022. The duration of the zone is intended to protect the vessel and cargo and surrounding waterway from terrorist acts, sabotage or other subversive acts, accidents, or other events of a similar nature. No vessel or person will be permitted to enter the security zone without obtaining permission from the COTP or a designated representative.

Entry into the security zone is prohibited unless authorized by the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of USCG Sector Corpus Christi. Persons or vessels desiring to enter or pass through each zone must request permission from the COTP or a designated representative on VHF-FM channel 16 or by telephone at 361–939–0450. If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative. The COTP or a designated representative will inform the public through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/ or Marine Safety Information Bulletins (MSIBs) as appropriate for the enforcement times and dates for each security zone.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, duration, and location of the security zone. This rule will impact a small designated area of 500-yards around the moving vessel in

the Corpus Christi Ship Channel and La Quinta Channel as the vessel transit the channel over a four day period. Moreover, the rule allows vessels to seek permission to enter the zones.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the temporary security zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

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

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

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes. or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the FOR **FURTHER INFORMATION CONTACT** section above

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023-01 and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321-4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a moving security zone lasting for the duration of time that the M/V TENERGY is within the Corpus Christi Ship Channel and La Quinta Channel while loaded with cargo. It will prohibit entry within a 500 yard radius of M/V TENERGY while the vessel is transiting

loaded within Corpus Christi Ship Channel and La Quinta Channel. It is categorically excluded from further review under L60 in Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the ADDRESSES section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the FOR FURTHER INFORMATION CONTACT section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

 \blacksquare 2. Add § 165.T08–0929 to read as follows:

§ 165.T08-0929 Security Zone; Corpus Christi Ship Channel. Corpus Christi, TX.

- (a) Location. The following area is a security zone: All navigable waters encompassing a 500-yard radius around the M/V TENERGY while the vessel is in the Corpus Christi Ship Channel and La Quinta Channel.
- (b) Enforcement period. This section will be enforced from November 14, 2022, until November 17, 2022.
- (c) Regulations. (1) The general regulations in § 165.33 apply. Entry into the zone in paragraph (a) of this section is prohibited unless authorized by the Captain of the Port Sector Corpus Christi (COTP) or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of USCG Sector Corpus Christi.
- (2) Persons or vessels desiring to enter or pass through the zones must request

permission from the COTP Sector Corpus Christi on VHF–FM channel 16 or by telephone at 361–939–0450.

(3) If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

(d) Information broadcasts. The COTP or a designated representative will inform the public through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate of the enforcement times and dates for the security zone.

Dated: November 8, 2022.

J.B. Gunning,

Captain, U.S. Coast Guard, Captain of the Port Sector Corpus Christi.

[FR Doc. 2022–24823 Filed 11–9–22; 4:15 pm]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2022-0731]

RIN 1625-AA00

Safety Zone; Mission Bay Closure, San Diego, CA

AGENCY: Coast Guard, Department of Homeland Security (DHS). **ACTION:** Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain waters of Mission Bay near San Diego, California. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by the California Department of Fish and Wildlife (CDFW) Oil Spill Prevention and Response (OSPR) Sensitive Site Strategy Evaluation Program (SSSEP) boom deployment exercise. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector San Diego.

DATES: This rule is effective from 9 a.m. to noon on November 15, 2022. **ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov*, type USCG-2022-0731 in the "SEARCH" box and click

0731 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this

rulemaking, call or email LTJG Shera Kim, Waterways Management, U.S. Coast Guard Sector San Diego, Coast Guard; telephone 619–278–7656, email MarineEventsSD@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On November 15, 2022, the Coast guard will be working in conjunction with the California Department of Fish and Wildlife and local Oil Spill Response Organization ito conduct boom deployment exercises from 9 a.m. to noon. Contractors will bring up to 12000-feet of floating oil boom aboard a workboat and deploy Area Contingency Plan (ACP)-6 Geographic Response Strategies (GRS). The Captain of the Port Sector San Diego (COTP) has determined that potential hazards associated with the boom deployment exercise would be a safety concern for anyone within a 100-yard radius of the boom. The COTP is establishing a safety zone from 9 a.m. to noon on November 15, 2022.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within a 100-yard radius of the boom before, during, and after the scheduled event. The Coast Guard has rulemaking authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Coast Guard published a notice of proposed rulemaking (NPRM) titled "Safety Zone; Mission Bay Closure, San Diego, CA" at 87 FR 55974 (September 13, 2022). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this safety zone. During the comment period that ended October 13, 2022, we received zero comments.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest because immediate action is needed to respond to the potential safety hazards associated with the pipeline repair operations for the damaged pipeline.

III. Discussion of Rule

The COTP is establishing a safety zone from 9 a.m. until noon on November 15, 2022. The safety zone covers all navigable waters within 100 vards of a boom in Mission Bay located across the entrance channel from the shoreline north of Mariners Cove inlet to a point south of Mission Bay Drive bridge on the Quivira Basin shoreline. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled 9 a.m. until noon boom deployment exercise. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. A designated representative means a a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel designated by or assisting the Captain of the Port Sector San Diego (COTP) in the enforcement of the safety zone.

To seek permission to enter, contact the COTP or the COTP's representative by VHF Channel 16. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

The COTP or a designated representative will inform the public through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate of the enforcement times and dates for the safety zone.

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on safety zone being of a limited three hour duration, limited to a relatively small geographic area, and the presence of safety hazards in the area encompassing the Mission Bay Entrance.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended,

requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. This rule will not result in such an expenditure.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting 3 hours that prohibits entry within 100 yards of the boom. Normally, such actions are categorically excluded from further review under paragraph L60 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T11–0114 to read as follows:

§ 165.T11–0114 Safety Zone; Mission Bay, San Diego, CA.

(a) Location. The following area is a safety zone: Mission Bay located across the entrance channel from the shoreline north of Mariners Cove inlet to a point south of Mission Bay Drive bridge on the Quivira Basin shoreline.

(b) Definitions. As used in this section, designated representative means a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel designated by or assisting the Captain of the Port Sector San Diego (COTP) in the enforcement of the safety zone.

(c) Regulations. (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by VHF Channel 16. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) Enforcement period. This section will be enforced from 9 a.m. until noon on November 15, 2022

on November 15, 2022.

(e) Information broadcasts. The COTP or a designated representative will inform the public through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate of the enforcement times and dates for the safety zone.

Dated: November 4, 2022.

J.W. Spitler,

Captain, U.S. Coast Guard, Captain of the Port Sector San Diego.

[FR Doc. 2022–24664 Filed 11–10–22; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 11

[Docket No. PTO-C-2022-0028]

RIN 0651-AD62

Eliminating Continuing Legal Education Certification and Recognition for Patent Practitioners

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Interim final rule.

SUMMARY: The U.S. Patent and Trademark Office (USPTO or Office) amends the rules of practice in patent cases and the rules regarding the representation of others before the USPTO to eliminate provisions regarding voluntary continuing legal education (CLE) certification for registered patent practitioners and individuals granted limited recognition to practice in patent matters before the USPTO. After rules were published on August 3, 2020, providing that registered patent practitioners and persons granted limited recognition to practice in patent matters before the USPTO would be permitted to voluntarily certify completion of CLE to the Director of the Office of Enrollment and Discipline (OED Director) and that the OED Director could publish whether such persons had voluntarily certified, the USPTO indefinitely delayed implementation of the voluntary CLE

certification. After receiving and considering stakeholder feedback on the certification process and possible details regarding implementation, the USPTO has determined that it will not implement the voluntary CLE certification program at this time.

Effective date: November 14, 2022. Comment deadline date: Written comments on the interim final rule must be received on or before December 14, 2022.

ADDRESSES: For reasons of Government efficiency, comments on the interim final rule must be submitted through the Federal eRulemaking Portal at www.regulations.gov. To submit comments via the portal, commenters should enter docket number PTO-C-2022-0028 on the homepage and click "search." The site will provide search results listing all documents associated with this docket. Commenters can find a reference to this rule and click on the "Comment Now!" icon, complete the required fields, and enter or attach their comments. Comments on the interim final rule should be addressed to Will Covey, Deputy General Counsel and OED Director. Attachments to electronic comments will be accepted in Adobe® portable document format (PDF) or Microsoft Word® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal for additional instructions on providing comments via the portal. If electronic submission of or access to comments is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT: Will Covey, Deputy General Counsel and OED Director, at 571–272–4097.

SUPPLEMENTARY INFORMATION: The USPTO amends 37 CFR 11.11(a)(1) and (3) to eliminate provisions concerning the voluntary CLE certification for registered patent practitioners and persons granted limited recognition to practice in patent matters before the USPTO under 37 CFR 11.9.

On August 3, 2020, the USPTO published a final rule providing that registered patent practitioners and persons granted limited recognition to practice in patent matters before the USPTO would be permitted to voluntarily certify completion of CLE to the OED Director (Setting and Adjusting

Patent Fees During Fiscal Year 2020, 85 FR 46932). 37 CFR 11.11(a)(3). The final rule also provided that the OED Director may publish whether each registered patent practitioner or person granted limited recognition under 37 CFR 11.9 has voluntarily certified that they completed the specified amount of CLE in the preceding 24 months. 37 CFR 11.11(a)(1).

On October 9, 2020, the USPTO published proposed CLE guidelines with a request for comments (Proposed Continuing Legal Education Guidelines, 85 FR 64128). The USPTO received public comments through January 7, 2021. On June 10, 2021, the USPTO published a Federal Register Notice providing, inter alia, that the USPTO would proceed with the voluntary CLE certification in the spring of 2022 (New Implementation Date for Patent Practitioner Registration Statement and Continuing Legal Education Certification, 86 FR 30920). On December 16, 2021, after considering public comments received regarding the proposed CLE guidelines, the USPTO published another Federal Register Notice indefinitely delaying implementation of the voluntary CLE certification (New Implementation Date for Voluntary Continuing Legal Education Certification, 86 FR 71453).

After considering public comments, the USPTO has determined that the voluntary CLE certification and recognition for patent practitioners will not be implemented. The USPTO's decision is intended to reflect the Office's focus on the most impactful ways to positively affect the issuance of robust and reliable patents. The USPTO is advancing numerous measures, including working on additional training opportunities for both those at the USPTO and those who practice before the USPTO. The Office has also released detailed guidance, both for those within the USPTO and those who practice before the USPTO, and intends to release more. In addition, the Office hosts video sessions and provides written and other materials to educate those who practice before the USPTO on applicable cases and guidance and on any updates to USPTO practice. Many reputable organizations also provide CLE related to practice before the USPTO and the relevant case law. Much of that CLE is monitored and approved by state bars. The USPTO encourages practitioners to avail themselves of all materials relevant to their practice and add themselves to the relevant USPTO email lists. It is incumbent on all those who practice before the USPTO to do what is necessary to maintain professional competency. Indeed,

"patent prosecutors need to stay abreast of Office policy and procedures, court decisions, and changes in laws to comply with the Office's regulatory requirements under at least 37 CFR 11.5, 6, and 101." AIPLA Letter to USPTO on Proposed CLE Guidelines, January 7, 2021, at 5 (available at https://www.uspto.gov/sites/default/files/documents/AIPLA_Letter_to_USPTO_on_CLE_Guidance_010721_FINAL.pdf).

As to the prior ÚSPTO proposal that pro bono work may substitute for legal training, the USPTO actively encourages practitioners to engage in both. Pro bono participation does not substitute for any education necessary for practitioners to maintain professional competency or for patent prosecutors to comply with the Office's regulatory requirements under at least 37 CFR 11.5, 11.6, and 11.101. That said, active participation in patent, trademark, Patent Trial and Appeal Board, and Trademark Trial and Appeal Board pro bono programs is essential for ensuring that all those who can contribute to job creation, economic prosperity, and world problem-solving have access to the innovation ecosystem and have the ability to protect their intellectual property for their benefit and for the good of the country. The USPTO has worked with partners to expand pro bono programs and pro bono opportunities for those who practice before the USPTO, and encourages all such persons to actively engage.

In the future, the Office may reconsider CLE reporting for patent practitioners, and nothing in this rule is intended to restrict or prohibit such action in the future. Accordingly, the USPTO amends 37 CFR 11.11(a)(1) and (3) to eliminate provisions related to the voluntary CLE certification and recognition.

Discussion of Specific Rules

The USPTO amends § 11.11 to remove the last sentence in paragraph (a)(1) to reflect the elimination of the voluntary CLE certification for registered patent practitioners and individuals granted limited recognition to practice in patent matters before the USPTO under 37 CFR 11.9, and to remove the entirety of paragraph (a)(3).

Rulemaking Requirements

A. Administrative Procedure Act: This interim final rule removes the provisions that apply to voluntary CLE certification for registered patent practitioners and individuals granted limited recognition to practice in patent matters before the USPTO under 37 CFR 11.9. The changes in this rulemaking involve rules of agency practice and

procedure, and/or interpretive rules. See Perez v. Mortgage Bankers Ass'n, 135 S. Ct. 1199, 1204 (2015) (interpretive rules "advise the public of the agency's construction of the statutes and rules which it administers") (citations and internal quotation marks omitted); Nat'l Org. of Veterans' Advocates v. Sec'y of Veterans Affairs, 260 F.3d 1365, 1375 (Fed. Cir. 2001) (rule that clarifies interpretation of a statute is interpretive); Bachow Commc'ns Inc. v. FCC, 237 F.3d 683, 690 (D.C. Cir. 2001) (rules governing an application process are procedural under the Administrative Procedure Act); Inova Alexandria Hosp. v. Shalala, 244 F.3d 342, 350 (4th Cir. 2001) (rules for handling appeals are procedural where they do not change the substantive standard for reviewing claims).

Accordingly, prior notice and opportunity for public comment for the changes in this rulemaking are not required pursuant to 5 U.S.C. 553(b) or (c), or any other law. See Perez, 135 S. Ct. at 1206 (notice-and-comment procedures are not required when an agency "issue[s] an initial interpretive rule" or when it amends or repeals that interpretive rule); Cooper Techs. Co. v. Dudas, 536 F.3d 1330, 1336-37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), do not require notice-and-comment rulemaking for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice" (quoting 5 U.S.C. 553(b)(A))).

Moreover, the Office, pursuant to the authority at 5 U.S.C. 553(b)(B), finds good cause to adopt the changes in this interim final rule without prior notice and an opportunity for public comment, as such procedures would be contrary to the public interest. This interim final rule will remove the provisions related to voluntary CLE certification from the regulations at 37 CFR 11.11(a) to avoid any confusion as to the status of the program. Although the voluntary CLE certification program was codified in the regulations, it was never implemented, and no patent practitioner participated in the program. Implementing this interim rule without prior notice and an opportunity for public comment is in the public interest because the time needed to do so would further delay the removal of the regulations and could lead to confusion as to the current status of the program among practitioners who practice before the USPTO.

In addition, pursuant to the authority at 5 U.S.C. 553(d)(3), the Office finds good cause to adopt the changes in this interim final rule without the 30-day delay in effectiveness, as such delay

would be contrary to the public interest. Immediate implementation of the changes in this interim final rule is in the public interest because the time needed to provide the 30-day delay in effectiveness would further postpone the removal of the regulations and could lead to confusion among patent practitioners as to the current status of the program.

B. Regulatory Flexibility Act: For the reasons set forth in this rule, the Senior Counsel for Regulatory and Legislative Affairs, Office of General Law, of the USPTO has certified to the Chief Counsel for Advocacy of the Small Business Administration that the changes in this rule will not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. 605(b).

This interim final rule will eliminate the provisions related to voluntary CLE certification. Because the voluntary CLE certification program was never implemented, no registered patent practitioners or persons granted limited recognition to practice in patent matters before the USPTO will be affected. Accordingly, the changes are expected to be of minimal or no additional burden to those practicing before the Office, and this rulemaking will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 12866 (Regulatory Planning and Review): This rulemaking has been determined to be not significant for purposes of E.O. 12866 (Sept. 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The USPTO has complied with E.O. 13563 (Jan. 18, 2011). Specifically, the Office has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across Government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and

technological information and processes.

E. Executive Order 13132 (Federalism): This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under E.O. 13132 (Aug. 4, 1999).

F. Executive Order 13175 (Tribal Consultation): This rulemaking will not: (1) have substantial direct effects on one or more Indian tribes, (2) impose substantial direct compliance costs on Indian tribal governments, or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under E.O. 13175 (Nov. 6, 2000).

G. Executive Order 13211 (Energy Effects): This rulemaking is not a significant energy action under E.O. 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under E.O. 13211 (May 18, 2001).

H. Executive Order 12988 (Civil Justice Reform): This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden, as set forth in sections 3(a) and 3(b)(2) of E.O. 12988 (Feb. 5, 1996).

I. Executive Order 13045 (Protection of Children): This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under E.O. 13045 (Apr. 21, 1997).

J. Executive Order 12630 (Taking of Private Property): This rulemaking will not effect a taking of private property or otherwise have taking implications under E.O. 12630 (Mar. 15, 1988).

K. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), the USPTO will submit a report containing the interim final rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this rulemaking are not expected to result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this rulemaking is not expected to result in a "major rule" as defined in 5 U.S.C. 804(2).

L. Unfunded Mandates Reform Act of 1995: The changes in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of \$100 million (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of \$100 million (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. See 2 U.S.C. 1501

M. National Environmental Policy Act of 1969: This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. See 42 U.S.C. 4321 et seq.

N. National Technology Transfer and Advancement Act of 1995: The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions that involve the use of technical standards.

O. Paperwork Reduction Act of 1995: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) requires that the Office consider the impact of paperwork and other information collection burdens imposed on the public. This rulemaking does not involve information collection requirements that are subject to review and approval by the Office of Management and Budget under the Paperwork Reduction Act.

P. E-Government Act Compliance: The USPTO is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes.

List of Subjects in 37 CFR Part 11

Administrative practice and procedure, Inventions and patents, Lawyers, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the USPTO amends 37 CFR part 11 as follows:

PART 11—REPRESENTATION OF OTHERS BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE

■ 1. The authority citation for part 11 continues to read as follows:

Authority: 5 U.S.C. 500; 15 U.S.C. 1123; 35 U.S.C. 2(b)(2), 32, 41; Sec. 1, Pub. L. 113–227, 128 Stat. 2114.

§11.11 [Amended]

- 2. Amend § 11.11 by:
- a. Removing from paragraph (a)(1) the last sentence; and
- b. Removing paragraph (a)(3).

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2022–24676 Filed 11–10–22; 8:45 am] BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R09-OAR-2022-0131; FRL-9739-02-R9]

Clean Air Plans; Base Year Emissions Inventories for the 2015 Ozone Standards; Nevada; Clark County, Las Vegas Valley

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving, under the Clean Air Act (CAA or "Act"), revisions to the Nevada state implementation plan (SIP) concerning the base year emissions inventory requirements for the Las Vegas Valley ozone nonattainment area for the 2015 ozone national ambient air quality standards (NAAQS or "standards").

DATES: This rule is effective December 15, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-R09-OAR-2022-0131. All documents in the docket are listed on the https://www.regulations.gov website. Although listed in the index, some information is not publicly available, e.g., confidential business information (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 form. Publicly available docket materials are available through https:// www.regulations.gov, or please contact the person identified in the FOR FURTHER **INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable

accommodation at no cost to you, please contact the person identified in the FOR FURTHER INFORMATION CONTACT section.

FOR FURTHER INFORMATION CONTACT:

Lindsay Wickersham, Air Planning Office (AIR–2), EPA Region IX, (415) 947–4192, wickersham.lindsay@ epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, "we," "us," and "our" refer to the EPA.

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IV. Statutory and Executive Order Reviews

I. Proposed Action

On October 15, 2020, the Nevada Department of Environmental Protection (NDEP) submitted a revision to the Nevada SIP titled, "Revision to the Nevada State Implementation Plan for the 2015 Ozone NAAQS: Emissions Inventory and Emissions Statement Requirements" ("2020 Clark County EI"). The 2020 Clark County EI submittal includes a 2017 base year emissions inventory for the Las Vegas Valley nonattainment area and supporting documentation regarding the development of the inventory, developed by the Clark County Department of Environment and Sustainability (CCDES). CCDES provided supplementary information to the 2020 Clark County EI on February 10, 2022, February 14, 2022, and March 30, 2022, to address comments and questions raised by the EPA on receipt of CCDES's prior submittal. Together these three supplementary exchanges are known as the "2020 Clark County SI."

On June 13, 2022, the EPA proposed to approve the 2020 Clark County EI and the 2020 Clark County SI as meeting the ozone-related base year emissions inventory requirement for the Las Vegas Valley ozone nonattainment area for the 2015 ozone NAAQS.1 Our June 13, 2022 proposed rule also discussed the following: background on the 2015 ozone NAAQS; an overview of the base vear emissions inventory requirements for the 2015 ozone NAAQS under sections 172(c)(3) and 182(a)(1) of the CAA and under the EPA's implementing regulations for the 2015 ozone NAAQS at 40 CFR 51.1315; an overview of NDEP's SIP revisions submitted to meet the ozone base year emissions inventory requirement for the Las Vegas Valley nonattainment area; a discussion of the

¹87 FR 35705.

public notice and hearing procedures conducted by NDEP to meet the requirements of CAA sections 110(a)(1) and 110(l) and 40 CFR 51.102; and our evaluation of NDEP's SIP submittals.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period that ended on July 13, 2022. During this period, we received one comment on our proposed rulemaking submitted from a private individual.² This comment is available in the docket for this rulemaking.³

A. Comment Summary

The comment letter from a private individual expresses concern that increased combustion of fossil fuels in Clark County is largely responsible for the area's worsening air quality in recent years. The commentor also expresses concern that Congressional legislation may result in the sale of federal lands in Clark County, promoting urban sprawl, and thus increased combustion of fossil fuels. The commentor emphasizes a need for this additional sprawl to be factored into Nevada's calculations of a "safe level of ozone emissions" and "believe(s) that the likelihood of continued urban sprawl in the county should be relevant to the accuracy and credibility of these calculations."4 Finally, the commenter states their belief that this urban sprawl will slow the transition away from fossil fuels and towards clean renewable energy sources.

B. EPA Response

The EPA appreciates the commenter's concern about how potential changes in the Las Vegas Valley nonattainment area (NAA) may lead to increased combustion of fossil fuels in the NAA. As discussed in the proposed notice, emissions inventories are an estimation of actual emissions of air pollutants within the NAA that are currently typical of an ozone season day. Base year emissions inventories, such as the 2020 Clark County EI are, "the starting point from which other SIP-related inventories are derived" and "provides a way for decision makers to consider

the sources of emissions that contribute to relevant pollutants and consider emission reduction strategies needed for the SIP." ⁶ As such, emissions inventories provide emissions data that inform a variety of a state's air quality planning tasks, and represent a required element under the CAA for areas that are not attaining the NAAQS established by the EPA. The 2020 Clark County EI was submitted to comply with the emissions inventory requirements for "Marginal" nonattainment areas for the 2015 ozone standard.7 Thus this emissions inventory is not intended for use in developing a "safe level of emissions" but rather to characterize emissions in the base year as required under the CAA.8 The base year emissions inventory is for a year in the recent past; it does not include the effects of future growth. Instead, it represents emissions at a snapshot in time. The emissions inventory in the 2020 Clark County EI represents the typical ozone season day emissions from 2017 within the existing nonattainment area boundary and does not consider future urban growth nor future emissions

The commentor seems to suggest that air quality in the Las Vegas Valley NAA has worsened in recent years. Although not directly relevant to whether it is appropriate for EPA to approve the SIP revision at issue in this action, we note that although the 2018 design value (DV) was higher than the 2017 DV, the 2019, 2020, and 2021 DVs remained at or below the 2017 DV of 0.074 ppm.⁹ While some fluctuations in DVs have occurred, the last 5 years of DVs do not indicate a trend of worsening ozone air quality in the NAA.

As noted, this action only concerns approval of the emissions inventory submitted for the Las Vegas Valley NAA for the 2015 ozone NAAQS. Although not directly relevant to whether such a SIP revision is appropriately approved by the EPA, the Agency notes that on July 22, 2022, the EPA proposed to reclassify the Las Vegas Valley NAA as "Moderate" for the 2015 ozone NAAQS. 10 If finalized, Clark County will be required to submit a Moderate plan which provides for, "such specific annual reductions in emissions as necessary to attain the primary NAAQS

by the attainment date applicable under this act." 11 Future growth within the NAA and potential growth of emissions will be projected and accounted for in this demonstration of attainment. The demonstration of attainment will include motor vehicle emissions budgets ("budgets"), which represent the levels of nitrogen oxides (NO_X) and volatile organic compound (VOC) emissions from motor vehicles in the 2023 attainment year that are consistent with attaining the 2015 ozone NAAQS. After the budgets are either found adequate or are approved by the EPA, they will be used by the metropolitan planning organization (MPO) for the Las Vegas Valley NAA in future transportation conformity determinations. When the MPO makes transportation conformity determinations, it must project on-road emissions of NO_X and VOCs through the last year of the MPO's transportation plan, which is at least 20 years into the future, and demonstrate that the projected emissions are less than or equal to the budgets. 12 This will show that even if there is increased travel within the Las Vegas Valley NAA in the future, emissions of NOx and VOCs will not increase above levels that are consistent with attaining the 2015 ozone NAAOS.

Based on our review of the 2020 Clark County EI, we have determined that the submitted emissions inventory adequately addresses all emission sources within the Las Vegas Valley NAA as of the submission date of October 15, 2020. Any future new or expanded emissions source within the NAA will be subject to control mandates as outlined in the CAA. 13 For example. as a Marginal nonattainment area, the New Source Review Program will ensure all new and modified major sources in the NAA will offset emissions at a ratio of 1 to 1.1.14 Additionally, all major sources within the NAA will be required to report annual emissions, and these emissions will be included in future modeling and attainment calculations related to the Las Vegas Valley NAA.15

For these reasons, we have determined that the 2020 Clark County EI meets the statutory and regulatory requirements for emission inventories. Control mandates and planning requirements for Marginal areas are adequate to ensure that any new sources within the NAA are accounted for in

 $^{^{2}\!}$ Comment dated June 13, 2022, from Richard Spotts.

³ Comments are publicly available at https://www.regulations.gov/docket/EPA-R09-OAR-2022-0131/comments.

⁴ Id.

⁵ EPA, Emissions Inventory Guidance for Implementation of Ozone and Particulate Matter National Ambient Air Quality Standards (NAAQS) and Regional Haze Regulations, May 2017, Section 2.5.2, Section 3.3.

 $^{^6\,\}mathrm{Id}.$ Section 3.3.

⁷80 FR 65292.

⁸CAA Section 182(a)(1).

⁹ The Las Vegas Valley 8-hour ozone DVs for 2017, 2018, 2019, 2020, and 2021 were 0.074 parts per million (ppm), 0.076 ppm, 0.073 ppm, 0.074 ppm, and 0.073 ppm respectively. EPA, Ozone Design Value Reports, https://www.epa.gov/airtrends/air-quality-design-values.

^{10 87} FR 43764 (July 22, 2022).

¹¹ CAA Section 182(b)(1).

^{12 40} CFR 93.106(a)(1)(iv) and 40 CFR 93.118(a).

¹³ CAA Section 182(a)(2)(C), 182(a)(3)(B).

¹⁴ CAA Section 182(a)(4).

¹⁵ CAA Section 182(a)(3)(b).

future emissions estimates and modeling.¹⁶

III. EPA Action

For the reasons described in our June 13, 2022 proposed action, we are taking final action to approve the 2020 Clark County EI as meeting the base year emissions inventory requirement for the Las Vegas Valley ozone nonattainment areas for the 2015 ozone NAAQS. The emissions inventory in the 2020 Clark County EI submittal and additional information collected in the 2020 Clark County SI contains comprehensive, accurate, and current inventories of actual emissions for all relevant sources in accordance with CAA sections 172(c)(3) and 182(a).

IV. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive

Order 13132 (64 FR 43255, August 10, 1999);

- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

The state did not evaluate environmental justice considerations as part of its SIP submittal. There is no information in the record inconsistent with the stated goals of Executive Order 12898 of achieving environmental justice for people of color, low-income populations, and indigenous peoples.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. The Las Vegas Tribe of Paiute Indians of the Las Vegas Indian Colony have areas of Indian country located within the Las Vegas Valley nonattainment area for the 2015 ozone NAAOS. In those areas of Indian country, this final rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small **Business Regulatory Enforcement** Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the Federal Register. A major rule cannot take effect until 60 days after it is published in the Federal Register. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 13, 2023. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 $et\ seq.$

Dated: October 19, 2022.

Martha Guzman Aceves,

Regional Administrator, Region IX.

For the reasons stated in the preamble, the EPA amends chapter I, title 40 of the Code of Federal Regulations as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart DD—Nevada

■ 2. In § 52.1470(e), amend the table under the heading "AIR QUALITY IMPLEMENTATION PLAN FOR THE STATE OF NEVADA," by adding an entry for "Revision to 2015 Eight-Hour Ozone Plan, Emissions Inventory Requirement for the Las Vegas Valley Nonattainment Area, Clark County, NV (October 15, 2020)" before the entry for "PM–10 State Implementation Plan for Clark County, June 2001" to read as follows:

§ 52.1470 Identification of plan.

(e) * * * * *

¹⁶CAA Section 182(a).

EPA-APPROVED NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES

Name of SIP provision

Applicable geographic or non-attainment area

State submittal date

EPA approval

Explanation

AIR QUALITY IMPLEMENTATION PLAN FOR THE STATE OF NEVADA 1

Revision to Nevada 2015 Eight-Hour Ozone Plan, Emissions Inventory Requirement for the Las Vegas Valley Nonattainment Area, Clark County, NV (October 15, 2020).

Las Vegas Valley, Clark County. 10/15/2020 11/14/2022, [INSERT FEDERAL REGISTER CITATION]. Adopted by the Clark County Board of County Commissioners on September 1, 2020. Submitted by NDEP electronically on October 15, 2020, as an attachment to a letter dated October 8, 2020. Approval of the Base-Year Emissions Inventory for the 2015 Eight Hour ozone NAAQS.

* * * * * * *

[FR Doc. 2022–23345 Filed 11–10–22; 8:45 am] **BILLING CODE 6560–50–P**

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[EPA-HQ-OW-2018-0594; FRL-7251-02-

Drinking Water Contaminant Candidate List 5—Final

AGENCY: Environmental Protection Agency (EPA).

ACTION: Availability of list.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is issuing the Contaminant Candidate List (CCL) which is a list of contaminants in drinking water that are currently not subject to any proposed or promulgated national primary drinking water regulations. In addition, these contaminants are known or anticipated to occur in public water systems and may require regulation under the Safe Drinking Water Act (SDWA). This list is the Fifth Contaminant Candidate List (CCL 5) published by the agency since the SDWA amendments of 1996. CCL 5 includes 66 chemicals, 3 chemical groups (cyanotoxins, disinfection byproducts (DBPs), and per- and polyfluoroalkyl substances (PFAS)), and 12 microbial contaminants.

DATES: November 14, 2022.

FOR FURTHER INFORMATION CONTACT: For information on chemical contaminants contact Kesha Forrest, Office of Ground Water and Drinking Water, Standards

and Risk Management Division, at (202) 564–3632 or email forrest.kesha@epa.gov. For information on microbial contaminants contact Nicole Tucker, Office of Ground Water and Drinking Water, Standards and Risk Management Division, at (202) 564–1946 or email tucker.nicole@epa.gov.

For more information visit *https://www.epa.gov/ccl.*

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¹The organization of this table generally follows from the organization of the State of Nevada's original 1972 SIP, which was divided into 12 sections. Nonattainment and maintenance plans, among other types of plans, are listed under Section 5 (Control Strategy). Lead SIPs and Small Business Stationary Source Technical and Environmental Compliance Assistance SIPs are listed after Section 12 followed by nonregulatory or quasi-regulatory statutory provisions approved into the SIP. Regulatory statutory provisions are listed in 40 CFR 52.1470(c).

I. General Information

A. Does this action impose any requirements on public water systems?

The Contaminant Candidate List 5 (CCL 5) does not impose any requirements on regulated entities.

- B. How can I get copies of this document and other related information?
- 1. Docket. EPA has established a docket for this action under Docket ID No. EPA-HQ-OW-2018-0594. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically through www.regulations.gov or in hard copy at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m. to 4:30 p.m., Monday through Friday (except Federal Holidays). For further information on the EPA Docket Center services and the current status, see: https://www.epa.gov/dockets.
- 2. Electronic Access. You may access this **Federal Register** document electronically from https://www.federalregister.gov/documents/current
- C. What is the purpose of this action?

The Safe Drinking Water Act (SDWA), as amended in 1996, requires EPA to publish a list every five years of currently unregulated contaminants that may pose risks for drinking water (referred to as the Contaminant Candidate List, or CCL). This list is subsequently used to make regulatory determinations on whether or not to regulate at least five contaminants from the CCL with national primary drinking water regulations (NPDWRs) ((SDWA section 1412(b)(1)). The purpose of this action is to publish the CCL 5, a summary of the major comments received on the draft CCL 5, and a summary of EPA's responses to those comments. Today's action only addresses the CCL 5. The Regulatory Determination (RD) process for contaminants on the CCL is a separate agency action.

- D. Background and Statutory Requirements for CCL, Regulatory Determination and Unregulated Contaminant Monitoring Rule
- 1. Contaminant Candidate List SDWA section 1412(b)(1)(B)(i), as amended in 1996, requires EPA to

publish the CCL every five years. The SDWA specifies that the list must include contaminants that are not subject to any proposed or promulgated NPDWRs, are known or anticipated to occur in public water systems (PWSs), and may require regulation under the SDWA. The unregulated contaminants considered for listing shall include, but not be limited to, hazardous substances identified in section 101(14) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, and substances registered as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The statute requires EPA to consult with the scientific community, including the Science Advisory Board (SAB) and to provide notice and opportunity for public comment. The SDWA directs EPA to consider the health effects and occurrence information for unregulated contaminants to identify those contaminants that present the greatest public health concern related to exposure from drinking water. The statute further directs EPA to take into consideration the effect of contaminants upon subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly, and individuals with a history of serious illness or other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population. EPA considers agerelated subgroups as "lifestages" in reference to a distinguishable time frame in an individual's life characterized by unique and relatively stable behavioral and/or physiological characteristics that are associated with development and growth. Thus, childhood is viewed as a sequence of stages, from conception through fetal development, infancy, and adolescence (USEPA, 2021a).

2. Regulatory Determination

SDWA section 1412(b)(1)(B)(ii), as amended in 1996, requires EPA, at five-year intervals, to make determinations of whether or not to regulate no fewer than five contaminants from the CCL. The 1996 SDWA Amendments specify three criteria to determine whether a contaminant may require regulation:

- The contaminant may have an adverse effect on the health of persons;
- The contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and

• In the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

If, after considering public comment on a preliminary determination, EPA makes a determination to regulate a contaminant, the agency will initiate the process to propose an NPDWR.¹ In that case, the statutory time frame provides for EPA proposal of a regulation within 24 months and action on a final regulation within 18 months of proposal (with a possible extension of 9 months).

3. Unregulated Contaminant Monitoring Rule

SDWA section 1445(a)(2), as amended in 1996, requires that once every five years, beginning in 1999, EPA issue a new list of no more than 30 unregulated contaminants to be monitored in drinking water by PWSs. This is known as the Unregulated Contaminant Monitoring Rule (UCMR). Monitoring is required by all PWSs serving more than 10,000 persons. The America's Water Infrastructure Act of 2018 expanded the requirements of the UCMR program and specifies that, subject to availability of appropriations and laboratory capacity, the UCMR program shall include all systems serving between 3,300 and 10,000 persons, and a nationally representative sample of PWSs serving fewer than 3,300 persons. The program would continue to require monitoring by PWSs serving more than 10,000 persons.

The SDWA also requires EPA to enter the monitoring data into the publicly available National Contaminant Occurrence Database (NCOD). This national occurrence data is used to inform regulatory decisions and nonregulatory public health protection actions for emerging contaminants in drinking water. EPA has issued five UCMRs; UCMR 1 was published on September 17, 1999 (64 FR 50556, USEPA, 1999), UCMR 2 was published on January 4, 2007 (72 FR 368, USEPA, 2007), UCMR 3 was published on May 2, 2012 (77 FR 26072, USEPA, 2012), UCMR 4 was published on December 20, 2016 (81 FR 92666, USEPA, 2016a), and UCMR 5 on December 27, 2021 (86 FR 73131, USEPA, 2021b). UCMR 5 requires monitoring for 30 chemical

¹ An NPDWR is a legally enforceable standard that applies to public water systems. An NPDWR sets a legal limit (called a maximum contaminant level or MCL) or specifies a certain treatment technique for public water systems for a specific contaminant or group of contaminants. The MCL is the highest level of a contaminant that is allowed in drinking water and is set as close to the MCLG as feasible, using the best available treatment technology and taking cost into consideration.

contaminants between 2023 and 2025 using analytical methods developed by EPA or consensus organizations.
Consistent with EPA's PFAS Strategic Roadmap (USEPA, 2021c), UCMR 5 will provide new data to improve the agency's understanding of the concentrations and the frequencies that 29 per- and polyfluoroalkyl substances (PFAS) and lithium occur in the nation's PWS; PFAS (as a group) and lithium are included on CCL 5.

E. Interrelationship Between CCL, Regulatory Determination, and Unregulated Contaminant Monitoring Rule

The CCL is the first step in the SDWA regulatory framework for screening and evaluating a subset of contaminants that may require future regulation. The CCL serves as the initial screening of potential contaminants for consideration under EPA's Regulatory Determination (RD) process. However, inclusion on the CCL does not mean that any particular contaminant will necessarily be regulated in the future. A decision to exclude a contaminant from a CCL may be reconsidered during future CCL cycles and that contaminant could potentially be listed if new information indicates that the contaminant meets the SDWA requirements for listing.

The UCMR provides a mechanism to obtain nationally representative occurrence data for contaminants in drinking water. Traditionally, unregulated contaminants chosen by EPA for monitoring have been selected from the most current CCL. When selecting contaminants for monitoring under the UCMR, EPA considers the availability of health effects data and the need for national occurrence data for contaminants, as well as analytical method availability, availability of analytical standards, sampling costs, and laboratory capacity to support a nationwide monitoring program. The contaminant occurrence data collected under UCMR serves to better inform future CCLs and regulatory determinations. Contaminants on the CCL are evaluated based on health effects and occurrence information and those contaminants with sufficient information to make a regulatory determination are then evaluated based on the three statutory criteria in SDWA section 1412(b)(1) to determine whether a regulation is required (called a positive determination) or not required (called a negative determination). Under the SDWA, EPA must make regulatory determinations for at least five contaminants listed on the CCL every five years. For those contaminants

without sufficient information to allow EPA to make a regulatory determination, the agency encourages research to provide the information needed to fill the data gaps to determine whether to regulate the contaminant. This action addresses only the CCL 5 and not Regulatory Determination or UCMR.

F. Summary of Previous CCLs and Regulatory Determinations

1. The First Contaminant Candidate List

The First Contaminant Candidate List (CCL 1) was published on March 2, 1998 (63 FR 10274, USEPA, 1998). The CCL 1 was developed based on recommendations by the National Drinking Water Advisory Council (NDWAC) and reviewed by technical experts. It contained 50 chemicals and 10 microbial contaminants/groups.

2. The Regulatory Determinations for CCL 1 Contaminants

EPA published its final regulatory determinations for a subset of contaminants listed on the CCL 1 on July 18, 2003 (68 FR 42898, USEPA, 2003). EPA identified 9 contaminants from the 60 contaminants listed on the CCL 1 that had sufficient data and information available to make regulatory determinations. The nine contaminants were Acanthamoeba, aldrin, dieldrin, hexachlorobutadiene, manganese, metribuzin, naphthalene, sodium, and sulfate. EPA determined that no regulatory action was appropriate or necessary for any of the nine contaminants at that time. EPA subsequently issued guidance on Acanthamoeba and Health Advisories for manganese, sodium, and sulfate.

3. The Second Contaminant Candidate

EPA published the Second Contaminant Candidate List (CCL 2) on February 24, 2005 (70 FR 9071, USEPA, 2005). EPA carried forward the 51 remaining chemical and microbial contaminants from the CCL 1 (that did not have regulatory determinations) to the CCL 2.

4. The Regulatory Determinations for CCL 2 Contaminants

EPA published its final regulatory determinations for a subset of contaminants listed on the CCL 2 on July 30, 2008 (73 FR 44251, USEPA, 2008). EPA identified 11 contaminants from the 51 contaminants listed on the CCL 2 that had sufficient data and information available to make regulatory determinations. The 11 contaminants were boron, the dacthal mono- and diacid degradates, 1,1-dichloro-2,2-bis (p-chlorophenyl) ethylene (DDE), 1,3-

dichloropropene, 2,4-dinitrotoluene, 2,6-dinitrotoluene, s-ethyl propylthiocarbamate (EPTC), fonofos, terbacil, and 1,1,2,2-tetrachloroethane. EPA made a final determination that no regulatory action was appropriate or necessary for any of the 11 contaminants. New or updated Health Advisories were subsequently issued for: boron, the dacthal degradates, 2,4-dinitrotoluene, 2,6-dinitrotoluene, and 1,1,2,2-tetrachloroethane.

5. The Third Contaminant Candidate List

EPA published the Third Contaminant Candidate List (CCL 3) on October 8, 2009 (74 FR 51850, USEPA, 2009). In developing the CCL 3, EPA implemented an improved, stepwise process which built on the previous CCL process and was based on expert input and recommendations from the National Academy of Sciences' National Research Council (NRC), the National Drinking Water Advisory Council (NDWAC), and the Science Advisory Board (SAB). The CCL 3 contained 104 chemicals or chemical groups and 12 microbial contaminants.

6. The Regulatory Determinations for CCL 3 Contaminants

EPA published a positive determination that perchlorate (a CCL 3 contaminant) met the criteria for regulating a contaminant under the SDWA based upon the information available at that time on February 11, 2011 (76 FR 7762, USEPA, 2011). EPA published final determinations not to regulate four additional CCL 3 contaminants—dimethoate, 1,3dinitrobenzene, terbufos and terbufos sulfone on January 4, 2016 (81 FR 13, USEPA, 2016b). EPA published a proposed rulemaking for perchlorate on June 26, 2019 (85 FR 43990, USEPA, 2019a), and sought public input on regulatory alternatives for perchlorate, including withdrawal of the previous positive regulatory determination. Based on the evaluation of public comments, and review of the updated scientific data, EPA withdrew the 2011 positive regulatory determination and made a final determination not to regulate perchlorate on July 21, 2020 (85 FR 43990, USEPA, 2020). EPA has since completed a review for the final determination for perchlorate in accordance with President Biden's Executive Order 13990 "Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis" (86 FR 7037, Executive Office of the President, 2021). On March 21, 2022, the agency concluded that the 2020 decision not to regulate

perchlorate is supported by the best available peer reviewed science. Additionally, EPA announced multiple integrated actions to ensure that public health is protected from perchlorate in drinking water.

7. The Fourth Contaminant Candidate

EPA published the Fourth Candidate List (CCL 4) on November 17, 2016 (81 FR 81099, USEPA, 2016c). CCL 4 contained 97 chemicals or chemical groups and 12 microbial contaminants. All contaminants listed on CCL 4 were carried forward from CCL 3, except for manganese and nonylphenol, which

were nominated by the public to be included on the CCL 4.

8. The Regulatory Determinations for CCL 4 Contaminants

EPA published final regulatory determinations for eight CCL 4 contaminants on March 3, 2021 (86 FR 12272, USEPA, 2021d). EPA made final determinations to regulate perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) in drinking water and to not regulate the six contaminants 1,1-dichloroethane, acetochlor, methyl bromide (bromomethane), metolachlor, nitrobenzene, and 1,3,5-Trinitro-1,3,5-triazinane (RDX).

II. What is on EPA's drinking water Contaminant Candidate List 5?

CCL 5 includes 81 contaminants or contaminant groups (Exhibits 1a, 1b, and 1c). The list is comprised of 69 chemicals or chemical groups which include 66 chemicals, one group of cyanotoxins, one group of disinfection byproducts (DBPs), and one group of PFAS chemicals. The list also includes 12 microbes; specifically eight bacteria, three viruses, and one protozoa.

A. Chemical Contaminants

BILLING CODE 6560-50-P

Exhibit 1a—Chemical Contaminants on CCL 5

Chemical Name	CASRN ¹	DTXSID ²
1,2,3-Trichloropropane	96-18-4	DTXSID9021390
1,4-Dioxane	123-91-1	DTXSID4020533
17-alpha ethynyl estradiol	57-63-6	DTXSID5020576
2,4-Dinitrophenol	51-28-5	DTXSID0020523
2-Aminotoluene	95-53-4	DTXSID1026164
2-Hydroxyatrazine	2163-68-0	DTXSID6037807
6-Chloro-1,3,5-triazine-2,4-diamine	3397-62-4	DTXSID1037806
Acephate	30560-19-1	DTXSID8023846
Acrolein	107-02-8	DTXSID5020023
alpha-Hexachlorocyclohexane	319-84-6	DTXSID2020684
Anthraquinone	84-65-1	DTXSID3020095
Bensulide	741-58-2	DTXSID9032329
Bisphenol A	80-05-7	DTXSID7020182
Boron	7440-42-8	DTXSID3023922
Bromoxynil	1689-84-5	DTXSID3022162
Carbaryl	63-25-2	DTXSID9020247
Carbendazim (MBC)	10605-21-7	DTXSID4024729
Chlordecone (Kepone)	143-50-0	DTXSID1020770
Chlorpyrifos	2921-88-2	DTXSID4020458
Cobalt	7440-48-4	DTXSID1031040
Cyanotoxins ³	Multiple	Multiple
Deethylatrazine	6190-65-4	DTXSID5037494
Desisopropyl atrazine	1007-28-9	DTXSID0037495
Desvenlafaxine	93413-62-8	DTXSID40869118
Diazinon	333-41-5	DTXSID9020407
Dicrotophos	141-66-2	DTXSID9023914

Chemical Name	CASRN ¹	DTXSID ²
Dieldrin	60-57-1	DTXSID9020453
Dimethoate	60-51-5	DTXSID7020479
Disinfection byproducts (DBPs) ⁴	Multiple	Multiple
Diuron	330-54-1	DTXSID0020446
Ethalfluralin	55283-68-6	DTXSID8032386
Ethoprop	13194-48-4	DTXSID4032611
Fipronil	120068-37-3	DTXSID4034609
Fluconazole	86386-73-4	DTXSID3020627
Flufenacet	142459-58-3	DTXSID2032552
Fluometuron	2164-17-2	DTXSID8020628
Iprodione	36734-19-7	DTXSID3024154
Lithium	7439-93-2	DTXSID5036761
Malathion	121-75-5	DTXSID4020791
Manganese	7439-96-5	DTXSID2024169
Methomyl	16752-77-5	DTXSID1022267
Methyl tert-butyl ether (MTBE)	1634-04-4	DTXSID3020833
Methylmercury	22967-92-6	DTXSID9024198
Molybdenum	7439-98-7	DTXSID1024207
Nonylphenol	25154-52-3	DTXSID3021857
Norflurazon	27314-13-2	DTXSID8024234
Oxyfluorfen	42874-03-3	DTXSID7024241
Per- and polyfluoroalkyl substances (PFAS) ⁵	Multiple	Multiple
Permethrin	52645-53-1	DTXSID8022292
Phorate	298-02-2	DTXSID4032459
Phosmet	732-11-6	DTXSID5024261
Phostebupirim	96182-53-5	DTXSID1032482
Profenofos	41198-08-7	DTXSID3032464
Propachlor	1918-16-7	DTXSID4024274
Propanil	709-98-8	DTXSID8022111
Propargite	2312-35-8	DTXSID4024276
Propazine	139-40-2	DTXSID3021196
Propoxur	114-26-1	DTXSID7021948
Quinoline	91-22-5	DTXSID1021798
Tebuconazole	107534-96-3	DTXSID9032113
Terbufos	13071-79-9	DTXSID2022254
Thiamethoxam	153719-23-4	DTXSID2034962
Tri-allate	2303-17-5	DTXSID5024344
Tribufos	78-48-8	DTXSID1024174
Tributyl phosphate	126-73-8	DTXSID3021986
Trimethylbenzene (1,2,4-)	95-63-6	DTXSID6021402
Tris(2-chloroethyl) phosphate (TCEP)	115-96-8	DTXSID5021411
Tungsten	7440-33-7	DTXSID8052481
Vanadium	7440-62-2	DTXSID2040282

¹ Chemical Abstracts Service Registry Number (CASRN) is a unique identifier assigned by the Chemical Abstracts Service (a division of the American Chemical Society) to

every chemical substance (organic and inorganic compounds, polymers, elements, nuclear particles, etc.) in the open scientific literature. It contains up to 10 digits, separated by hyphens into three parts.

- ² Distributed Structure Searchable Toxicity Substance Identifiers (DTXSID) is a unique substance identifier used in EPA's CompTox Chemicals database, where a substance can be any single chemical, mixture or polymer.
- ³ Toxins naturally produced and released by some species of cyanobacteria (previously known as "blue-green algae"). The group of cyanotoxins includes, but is not limited to: anatoxin-a, cylindrospermopsin, microcystins, and saxitoxin.
- ⁴ This group includes 23 unregulated DBPs as shown in Exhibit 1b.
- ⁵ For the purpose of CCL 5, the structural definition of per- and polyfluoroalkyl substances (PFAS) includes chemicals that contain at least one of these three structures (except for PFOA and PFOS which are already in the regulatory process):
 - 1. R-(CF2)-CF(R')R", where both the CF2 and CF moieties are saturated carbons, and none of the R groups can be hydrogen
 - 2. R-CF2OCF2-R', where both the CF2 moieties are saturated carbons, and none of the R groups can be hydrogen
 - 3. CF3C(CF3)RR', where all the carbons are saturated, and none of the R groups can be hydrogen

Exhibit 1b—Unregulated DBPs in the DBP Group on CCL 5

Chemical Name	CASRN	DTXSID
Haloacetic Acids		
Bromochloroacetic acid (BCAA)	5589-96-8	DTXSID4024642
Bromodichloroacetic acid (BDCAA)	71133-14-7	DTXSID4024644
Dibromochloroacetic acid (DBCAA)	5278-95-5	DTXSID3031151
Tribromoacetic acid (TBAA)	75-96-7	DTXSID6021668
Haloacetonitriles		
Dichloroacetonitrile (DCAN)	3018-12-0	DTXSID3021562
Dibromoacetonitrile (DBAN)	3252-43-5	DTXSID3024940
Halonitromethanes		
Bromodichloronitromethane (BDCNM)	918-01-4	DTXSID4021509
Chloropicrin (trichloronitromethane, TCNM)	76-06-2	DTXSID0020315
Dibromochloronitromethane (DBCNM)	1184-89-0	DTXSID00152114
Iodinated Trihalomethanes		
Bromochloroiodomethane (BCIM)	34970-00-8	DTXSID9021502
Bromodiiodomethane (BDIM)	557-95-9	DTXSID70204235
Chlorodiiodomethane (CDIM)	638-73-3	DTXSID20213251
Dibromoiodomethane (DBIM)	593-94-2	DTXSID60208040
Dichloroiodomethane (DCIM)	594-04-7	DTXSID7021570
Iodoform (triiodomethane, TIM)	75-47-8	DTXSID4020743
Nitrosamines		
Nitrosodibutylamine (NDBA)	924-16-3	DTXSID2021026
N-Nitrosodiethylamine (NDEA)	55-18-5	DTXSID2021028
N-Nitrosodimethylamine (NDMA)	62-75-9	DTXSID7021029
N-Nitrosodi-n-propylamine (NDPA)	621-64-7	DTXSID6021032
N-Nitrosodiphenylamine (NDPhA)	86-30-6	DTXSID6021030
Nitrosopyrrolidine (NPYR)	930-55-2	DTXSID8021062
Others		
Chlorate	14866-68-3	DTXSID3073137
Formaldehyde	50-00-0	DTXSID7020637

B. Microbial Contaminants

Exhibit 1c—Microbial Contaminants on CCL 5

Microorganism	Type of Microorganism
Adenovirus	Virus
Caliciviruses	Virus
Campylobacter jejuni	Bacteria
Escherichia coli (O157)	Bacteria
Enteroviruses	Virus
Helicobacter pylori	Bacteria
Legionella pneumophila	Bacteria
Mycobacterium abscessus	Bacteria
Mycobacterium avium	Bacteria
Naegleria fowleri	Protozoa
Pseudomonas aeruginosa	Bacteria
Shigella sonnei	Bacteria

III. Summary of the Approach Used To Identify and Select Candidates for the CCL 5

A. Overview of the Three-Step Development Process

EPA followed the stepwise process used in developing the CCL 3 and CCL 4, which was based on expert input and recommendations from the SAB, NRC and NDWAC. Note that EPA used an abbreviated process for the CCL 4 by carrying forward the CCL 3 contaminants (81 FR 81099, USEPA, 2016c). In each cycle of the CCL, EPA

attempts to improve the CCL development process in response to comments from the public and the SAB. Therefore, in developing the CCL 5, EPA implemented improvements to the CCL process to better identify, screen, and classify potential drinking water contaminants. EPA's approach utilizes the best available data to characterize the occurrence and adverse health risks a chemical may pose from potential drinking water exposure.

Exhibit 2 illustrates a generalized 3step process EPA applied to both chemical and microbial contaminants for the CCL 5. The agency began with a large Universe of contaminants, screened it down to a Preliminary CCL 5 (PCCL 5), selected the Draft CCL 5, then published for public comment. The specific execution of particular steps differed in detail for the chemical and microbial contaminants. Each step of the CCL 5 process and associated number of chemical and microbial contaminants are described in the remainder of Section III of this document.

			Number of Chemical Contaminants	Number of Microbial Contaminants
Building the Unive		STEP 1	~22,000	1,435
Screening	Preliminary CCL (PCCL)	STEP 2	275	35
Classification	CCL	STEP 3	66 individual + 3 groups	12

Exhibit 2—Generalized CCL 5 Development Process and Contaminant Counts

1. Chemical Contaminants

EPA followed the three-step process illustrated in Exhibit 2 to identify chemicals for inclusion on the CCL 5. These steps included:

- Step 1. Building a broad universe of potential drinking water contaminants (called the CCL 5 Chemical Universe). EPA evaluated 134 data sources and identified 43 that were related to potential drinking water chemical contaminants and met established CCL assessment factors. From these data sources, EPA identified and extracted occurrence and health effects data for the 21,894 chemicals that form the CCL 5 Chemical Universe.
- Step 2. Screening the CCL 5 Chemical Universe to identify a list of chemicals that should be further evaluated (called the Preliminary CCL 5 (PCCL 5)). EPA established and applied a data-driven screening points system to identify and prioritize a subset of chemicals with the greatest potential for public health concern. The agency also incorporated publicly nominated chemicals to the PCCL 5.
- Step 3. Classification of PCCL 5 chemicals to select the CCL 5 chemicals. EPA compiled occurrence and health effects information for use by two evaluation teams of EPA scientists. The evaluation teams reviewed this information for each chemical before reaching a group decision on whether to list a chemical on the CCL 5.

A detailed description of the processes used to develop the CCL 5 of chemicals using these steps can be found in the Technical Support Document for the Final Fifth Contaminant Candidate List (CCL 5)—Chemical Contaminants (USEPA, 2022a), referred to hereafter as the Final CCL 5 Chemical Technical Support Document.

2. Microbial Contaminants

EPA also followed the three-step process illustrated in Exhibit 2 to identify microbes for inclusion on the CCL 5. For microbial contaminants, these steps included:

- Step 1. Building a broad universe of all microbes that may cause human disease.
- Step 2. Screening that universe of microbial contaminants to produce a PCCL 5.
- Step 3. Selecting the CCL 5 microbial list by ranking the PCCL 5 contaminants based on occurrence in drinking water (including waterborne disease outbreaks) and human health effects.

This approach is similar to that used by EPA for the CCL 3, with updates made to the microbial screening process in response to a CCL 4 SAB recommendation. EPA re-examined all 12 microbial exclusionary screening criteria used in previous CCLs and modified one criterion for the CCL 5. A detailed description of these steps used to select microbes for the CCL 5 can be found in the Technical Support Document for the Final Fifth Candidate List (CCL 5)—Microbial Contaminants (USEPA, 2022b), referred to hereafter as the Final CCL 5 Microbial Technical Support Document.

B. Summary of Nominated Candidates for the CCL 5

EPA sought public nominations in a Federal Register notice (FRN) on October 5, 2018, for unregulated chemical and microbial contaminants to be considered for possible inclusion in the CCL 5 (83 FR 50364, USEPA, 2018a). EPA received nominations for 89 unique contaminants from 29 different organizations and/or individuals for the CCL 5, including 73 chemicals and 16 microbes. EPA compiled and reviewed the information from the nominations process to identify the nominated contaminants and any sources of supporting data submitted that could be used to supplement the data gathered by EPA to inform selection of the CCL 5. Nominated contaminants included chemicals used in commerce, pesticides, disinfection byproducts, pharmaceuticals, naturally occurring elements, biological toxins, and waterborne pathogens. Contaminants nominated for consideration for the CCL 5 are shown in Exhibits 3a and 3b. All public nominations can be viewed in the EPA docket at https:// www.regulations.gov (Docket ID No. EPA-HQ-OW-2018-0594). A more

detailed summary of the nomination process is included in Section 3.6 of the Final CCL 5 Chemical Technical

Support Document (USEPA, 2022a) and in Section 2.1 of the Final CCL 5

Microbial Technical Support Document (USEPA, 2022b).

Exhibit 3a—Chemical Contaminants Nominated for Consideration on CCL 5

Chemical Name	CASRN	DTXSID	
1,1-Dichloroethane	75-34-3	DTXSID1020437	
1,4-Dioxane	123-91-1	DTXSID4020533	
1-Phenylacetone ²	103-79-7	DTXSID1059280	
2-(N-Methylperfluorooctane sulfonamido)acetic acid (Me-PFOSA- AcOH)	2355-31-9	DTXSID10624392	
2-(N-Ethyl perfluorooctane sulfonamido) acetic acid (Et-PFOSA-AcOH)	2991-50-6	DTXSID5062760	
2-[(8-Chloro-1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8-Hexadecafluorooctyl)oxy]-1,1,2,2-tetrafluoroethane-1-sulfonic acid (11Cl-PF3OUdS)	763051-92-9	DTXSID40892507	
3-Hydroxycarbofuran	16655-82-6	DTXSID2037506	
3-Monoacetylmorphine ²	29593-26-8	DTXSID30183774	
4,8-Dioxa-3H-perfluorononanoic acid (ADONA)	919005-14-4	DTXSID40881350	
6-Monoacetylmorphine ²	2784-73-8	DTXSID60182154	
Ammonium perfluoro-2-methyl-3-oxahexanoate	62037-80-3	DTXSID40108559	
Anatoxin A	64285-06-9	DTXSID50867064	
Azinphos-methyl	86-50-0	DTXSID3020122	
Benzoic acid ²	65-85-0	DTXSID6020143	
Benzoic acid glucuronide ²	19237-53-7	DTXSID90940901	
Bromochloroacetic acid (BCAA)	5589-96-8	DTXSID4024642	
Bromochloroiodomethane (BCIM)	34970-00-8	DTXSID9021502	
Bromodichloroacetic acid (BDCAA)	71133-14-7	DTXSID4024644	
Bromodichloronitromethane (BDCNM)	918-01-4	DTXSID4021509	
Bromodiiodomethane (BDIM)	557-95-9	DTXSID70204235	
Chlorate	14866-68-3	DTXSID3073137	
Chloro-diiodo-methane (CDIM)	638-73-3	DTXSID20213251	
Chloropicrin (trichloro-nitromethane; TCNM)	76-06-2	DTXSID0020315	
Chlorpyrifos	2921-88-2	DTXSID4020458	

Chemical Name	CASRN	DTXSID
Cylindrospermopsin	143545-90-8	DTXSID2031083
Dibromochloracetic acid (DBCAA)	5278-95-5	DTXSID3031151
Dibromochloronitromethane (DBCNM)	1184-89-0	DTXSID00152114
Dibromoiodomethane (DBIM)	593-94-2	DTXSID60208040
Dichloroiodomethane (DCIM)	594-04-7	DTXSID7021570
Fluoxetine	5491-89-3	DTXSID7023067
Gemfibrozil	25812-30-0	DTXSID0020652
Heroin	561-27-3	DTXSID6046761
Hippuric acid ²	495-69-2	DTXSID9046073
Hydromorphone ²	466-99-9	DTXSID8023133
Hydromorphone-3-glucuronide ²	No CASRN	NO_DTXSID
Hydroxyamphetamide ²	103-86-6	DTXSID3023134
Isodrin (Pholedrine, 4- Hydroxymethamphetamine) ²	465-73-6	DTXSID7042065
Manganese	7439–96–5	DTXSID2024169
Methamphetamine ²	537-46-2	DTXSID8037128
Microcystin LA	96180-79-9	DTXSID3031656
Microcystin LR	101043-37-2	DTXSID3031654
Microcystin LW	No CASRN	DTXSID70891285
Microcystin RR	111755-37-4	DTXSID40880085
Microcystin YR	101064-48-6	DTXSID00880086
Molybdenum	7439–98–7	DTXSID1024207
Morphine	57-27-2	DTXSID9023336
Morphine-3-glucuronide	20290-09-9	DTXSID80174157
Morphine-6-glucuronide ²	20290-10-2	DTXSID40174158
N-Nitrosodiethylamine (NDEA)	55-18-5	DTXSID2021028
N-Nitrosodimethylamine (NDMA)	62-75-9	DTXSID7021029
N-Nitroso-di-n-propylamine (NDPA)	621-64-7	DTXSID6021032
N-Nitrosodiphenylamine (NDPhA)	86-30-6	DTXSID6021030
N-Nitrosopyrrolidine (NPYR)	930-55-2	DTXSID8021062
Perfluoro(2-((6-chlorohexyl)oxy)ethanesulfonic acid) (9Cl-PF3ONS)	756426-58-1	DTXSID80892506
Perfluoro-2-methyl-3-oxahexanoic acid	13252-13-6	DTXSID70880215
Perfluorobutane sulfonic acid (PFBS)	375-73-5	DTXSID5030030

Chemical Name	CASRN	DTXSID
Perfluorobutyric acid (PFBA)	375-22-4	DTXSID4059916
Perfluorodecanoic acid (PFDeA/PFDA)	335-76-2	DTXSID3031860
Perfluorododecanoic acid (PFDoA)	307-55-1	DTXSID8031861
Perfluoroheptanoic acid (PFHpA)	375-85-9	DTXSID1037303
Perfluorohexane sulfonic acid (PFHxS)	355-46-4	DTXSID7040150
Perfluorohexanoic acid (PFHxA)	307-24-4	DTXSID3031862
Perfluorononanoic acid (PFNA)	375-95-1	DTXSID8031863
Perfluorooctanesulfonamide (PFOSA)	754-91-6	DTXSID3038939
Perfluorooctane sulfonic acid (PFOS)	1763-23-1	DTXSID3031864
Perfluorooctanoic acid (PFOA)	335-67-1	DTXSID8031865
Perfluorotetradecanoic acid (PFTA) ¹	376-06-7	DTXSID3059921
Perfluorotridecanoic acid (PFTrDA) ¹	72629-94-8	DTXSID90868151
Perfluoroundecanoic acid (PFUA/PFUnA)	2058-94-8	DTXSID8047553
Phenylpropanolamine ²	37577-28-9	DTXSID4023466
Strontium	7440-24-6	DTXSID3024312
Tribromoacetic acid (TBAA)	75-96-7	DTXSID6021668
Triiodomethane (TIM)	75-47-8	DTXSID4020743

¹Other acronyms that may be used: Perfluorotetradecanoic acid (PFTetDA) and Perfluorotridecanoic acid (PFTriDA).

²Thirteen nominated chemicals did not have available water occurrence data, even after a systematic literature search was conducted, and therefore were not evaluated for listing on the CCL 5. See Section 4.2.1.1 of the Final CCL 5 Chemical Technical Support Document for more information.

Exhibit 3b—Microbial Contaminants Nominated for Consideration on CCL 5

Microorganism
Adenovirus
Aeromonas hydrophila
Caliciviruses
Campylobacter jejuni
Enterovirus
Escherichia coli (0157)
Helicobacter pylori
Hepatitis A virus
Legionella pneumophila
Mycobacterium species predominantly found in drinking water
Mycobacterium avium
Naegleria fowleri
Non-tuberculous Mycobacterium (NTM)
Pseudomonas aeruginosa
Salmonella enterica
Shigella sonnei

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1. Chemical Nominations and Listing Outcomes

EPA reviewed the 73 publicly nominated chemical contaminants and included 47 out of the 73 on the CCL 5. Four publicly nominated chemicals were included on the CCL 5 as a result of evaluation team listing decisions, including 1,4-dioxane, chlorpyrifos, manganese, and molybdenum. In addition, 43 nominated chemicals consisting of 7 cyanotoxins, 18 DBPs, and 18 PFAS chemicals were included in the three chemical groups listed on the CCL 5 (*i.e.*, the cyanotoxin, DBP, and PFAS groups).

To evaluate the chemical nominations, EPA first compared the publicly nominated chemical contaminants with the top 250th scored chemicals and identified 19 chemicals which were already included in the top 250 chemicals of the scored CCL 5 Chemical Universe and not subject to proposed or promulgated NPDWRs. If a nominated chemical was part of the top 250 chemicals, then EPA had already

identified and extracted health effects and occurrence data on this chemical from primary data sources in Step 1, Building the Chemical Universe. Some nominated chemicals were not included in the CCL 5 Chemical Universe; they would require further data collection to be evaluated for listing on the CCL 5. To identify additional data for these nominated chemicals, EPA assessed data sources cited with public nominations using the CCL-specific assessment factors (described in Section 2.2 of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a)) and extracted health effects and occurrence data from sources that were relevant, complete, and not redundant. Sources that met these three assessment factors were considered supplemental data sources and could serve as references to fill any data gaps for particular chemical contaminants during Step 3 of the CCL 5 process. EPA also conducted literature searches to identify additional health effects and occurrence data; more information on the literature searches can be found in

Section 4.2 of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a).

EPA could not identify occurrence data for 13 nominated chemicals (noted in Exhibit 3a) from either primary or supplemental data sources nor was data provided in the public nominations. Without available data regarding measured occurrence in water or relevant data provided by the nominators, the two evaluation teams agreed that they could not determine whether these chemicals were likely to present the greatest public health concern through drinking water exposure and therefore EPA should not advance these chemicals further in the CCL 5 process. However, four of these nominated chemicals were evaluated for possible research needs (see Chapter 5 of the Final CCL 5 Chemical Technical Support Document; USEPA, 2022a). More detailed information about how nominated chemicals were considered for CCL 5 can be found in Section 3.6 of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a).

2. Microbial Nominations and Listing Outcomes

EPA reviewed the nominated microbial contaminants to determine if the microorganisms nominated were already included as a part of the CCL 5 Microbial Universe. EPA also collected additional data, when available, for the nominated microbial contaminants from data sources and from literature searches covering the time between the CCL 4 and the CCL 5 (2016-2019). If new data were available, EPA screened and scored the microbial contaminants nominated for CCL 5 using the same process that was developed for the CCL 3. A more detailed description of the data sources used to evaluate microbial contaminants for the CCL 5 can be found in the Final CCL 5 Microbial Technical Support Document (USEPA, 2022b).

All microbes nominated for the CCL 5, except for Salmonella enterica, Aeromonas hydrophila, Hepatitis A, and Non-tuberculous Mycobacterium (NTM) as a group are listed on the CCL 5. Salmonella enterica, Aeromonas hydrophila and Hepatitis A did not produce sufficient composite scores to place them on the CCL 5. Although Salmonella enterica and Hepatitis A have numerous outbreaks reported in Centers of Disease Control (CDC) National Outbreak Reporting System (NORS), the route of exposure was not reported as waterborne in NORS. Nontuberculous Mycobacterium (NTM) and Mycobacterium (species broadly found in drinking water) were nominated for the CCL 5 and are not listed on the CCL 5 as a group; instead, two species of NTM that are found in drinking water, Mycobacterium avium and Mycobacterium abscessus, are listed.

C. Chemical Groups on the CCL 5

In addition to the 66 individual chemicals listed on the CCL 5, EPA is listing cyanotoxins, DBPs, and PFAS as chemical groups instead of listing them as individual chemicals. One of the primary goals of the CCL process is to identify priority contaminants for further evaluation under the regulatory determination process and/or additional research and data collection. These chemical groups meet the CCL SDWA requirements and were also identified as agency priorities and contaminants of concern for drinking water under other EPA actions. Therefore, EPA is listing these three groups on CCL 5. EPA's approach to listing cyanotoxins, DBPs, and PFAS as groups on CCL 5 as opposed to listing them as individual contaminants limits duplication of agency efforts, such as data gathering,

analyses and evaluations. Listing these three chemical groups on the CCL 5 does not necessarily mean that EPA will make subsequent regulatory decisions for the entire group. EPA will evaluate scientific data on the listed groups, subgroups, and individual contaminants included in the group to inform any regulatory determinations. When making a determination to regulate a group, subgroup, or individual contaminants in the group, EPA must evaluate the group, subgroup, or individual contaminants under the three criteria in SDWA Section 1412(b)(1)(A).

Addressing the public health concerns of cyanotoxins in drinking water remains an agency priority as specified in the 2015 Algal Toxin Risk Assessment and Management Strategic Plan for Drinking Water (USEPA, 2015). Cyanotoxins are toxins naturally produced and released by some species of cyanobacteria (previously known as ''blue-green algae''). Cyanotoxins were included on CCL 4 as an aggregate group in order to encompass all toxins produced by cyanobacteria (including, but not limited to, microcystins, cylindrospermopsin, anatoxin-a and saxitoxins). The reason for this decision, and as stated in CCL 4, is the similar sources of cyanotoxins (i.e., cyanobacteria) indicate their management may be similar. EPA listed cyanotoxins as a group on the CCL 5, identical to the CCL 4 listing.

From 2018 to 2021 under EPA's Fourth Unregulated Contaminant Monitoring Rule (UCMR 4) Program, EPA coordinated with public water systems on the collection and reporting of nationally-representative finished drinking water cyanotoxin occurrence data for 10 cyanotoxins/cyanotoxin congeners. The final UCMR 4 data were published on February 18, 2022. UCMR 4 resulted in a low percentage of detections above the reference concentration and/or the national drinking water health advisory levels for the cyanotoxins monitored under UCMR 4. However, there are cyanotoxins that were not monitored as a part of UCMR 4. Also, significant health effects data and/or occurrence data are lacking for many of them (e.g., euglenophycin and saxitoxins). The prevalence, duration and frequency of HABs in freshwater is expanding in the U.S. and HABs continue to present a challenge for many state and local drinking water programs. Therefore, cyanotoxins continue to pose a potential public health risk and remain listed as a group on CCL 5.

EPA is also listing 23 unregulated DBPs (as shown in Exhibit 2b) as a group on the CCL 5; either these DBPs

were publicly nominated, among the top 250 chemicals, or both. DBPs are formed when disinfectants react with naturally occurring materials in water. Under the Six-Year Review 3 (SYR 3), EPA identified 10 regulated DBPs (all but bromate) as "candidates for revision" (USEPA, 2017). EPA is conducting analyses to further evaluate the candidates for potential regulatory revisions identified under SYR 3 known as the Microbial Disinfection Byproducts (MDBP) Rule Revisions. Additionally, under the MDBP rule revisions effort, EPA is also evaluating information on unregulated DBPs.

PFAS are a class of synthetic chemicals that are most commonly used to make products resistant to water, heat, and stains and are consequently found in industrial and consumer products like clothing, food packaging, cookware, cosmetics, carpeting, and fire-fighting foam (AAAS, 2020; USEPA, 2018b). Over 4,000 PFAS may have been manufactured and used in a variety of industries worldwide since the 1940s (USEPA, 2019b). Additionally, chemical intermediates, degradates, processing aids, and by-products of PFAS manufacturing may also meet one or more of the structural definitions of PFAS making the listing of PFAS individually on the CCL 5 difficult and challenging. Listing PFAS as a group is responsive to public nominations which stated that EPA should "include PFAS chemicals as a class on CCL 5," and was supported by many public commenters and the SAB. EPA is listing PFAS as a group inclusive of any PFAS that fit the revised CCL 5 structural definition (except for PFOA and PFOS which have a proposed national primary drinking water regulation planned for late 2022). For the purposes of CCL 5, the structural definition of per- and polyfluoroalkyl substances (PFAS) includes chemicals that contain at least one of these three structures:

(1) R-(CF2)-CF(R')R", where both the CF2 and CF moieties are saturated carbons, and none of the R groups can be hydrogen.

(2) R-CF2OCF2-R', where both the CF2 moieties are saturated carbons, and none of the R groups can be hydrogen.
(3) CF3C(CF3)RR', where all the

(3) CF3C(CF3)RR', where all the carbons are saturated, and none of the R groups can be hydrogen.

EPA is also providing a list of PFAS that meet the CCL 5 structural definition (WATER|EPA: Chemical Contaminants—CCL 5 PFAS subset) on its CompTox dashboard (https://comptox.epa.gov/dashboard/chemical-

lists).

Listing PFAS as a group on CCL 5 supports the agency's commitment to

better understand and ultimately reduce the potential risks caused by this broad class of chemicals. It also demonstrates the agency's commitment to prioritizing and building a strong foundation of science on PFAS while working to harmonize multiple statutory authorities to address the impacts of PFAS on public health and the environment.

EPA is also aware there may be emerging contaminants such as fluorinated organic substances that may be used in or are a result of the PFAS manufacturing process (e.g., starting materials, intermediates, processing aids, by-products and/or degradates) that do not meet the structural definition. Those emerging PFAS contaminants or contaminant groups may be known to occur or are anticipated to occur in public water systems, and which may require regulation. If emerging PFAS contaminants or contaminant groups are identified, EPA may consider moving directly to the regulatory determination process or consider listing those contaminants for future CCL cycles. EPA will continue to be proactive in considering evolving occurrence and health effects data of these emerging contaminants.

IV. What comments did EPA receive on the Draft CCL 5 and how did the Agency respond?

A. Public Comments

With publication of the Draft CCL 5 in a **Federal Register** document on July 19, 2021 (86 FR 37948, USEPA, 2021e), EPA sought public comment on the following topics:

- 1. Contaminants that EPA selected for the Draft CCL 5, and any supporting data that could assist with developing the Final CCL 5.
- 2. Existing data that EPA obtained and evaluated for developing the Draft CCL 5
- 3. Improvements that EPA implemented for developing the Draft CCL 5.

The agency received a total of 54 unique comment letters from the public within the allotted 60-day comment period. EPA considered all public comments, data and information provided by commenters related to finalizing the CCL 5. EPA prepared responses to all public comments and included them in the "Comment Response Document for the Draft Fifth Drinking Water Contaminant Candidate List (CCL 5)—Categorized Public Comment)," which is available in the docket for this action (USEPA, 2022d). A summary of the public's comments

for the Draft CCL 5, along with EPA's responses, are provided in this section.

1. General Comments

EPA received many general comments related to the Draft Fifth Contaminant Candidate List (CCL 5), including comments supporting EPA's mission of protecting human health by continuing to regulate contaminants in drinking water and identifying drinking water contaminants that may require regulation. EPA also received multiple comments supporting the CCL purpose and process.

2. Chemical Process and Chemical Contaminants

EPA received multiple comments in support of continued improvements to CCL documentation, with several commenters recommending specific steps to facilitate transparency and clear communication of the CCL process. Two commenters requested that EPA expand on contaminants that appeared on CCL 4 but were not listed on CCL 5. In response to this comment EPA has provided a table in Appendix O of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a).

a. Chemical Data/Data Sources

EPA received two comments related to chemical data and data sources used in developing the CCL 5. This included a comment supporting the agency's use of preliminary Fourth Unregulated Contaminant Monitoring Rule (UCMR 4) data to develop the CCL 5 and the agency's "decision to no longer exclude chemicals that could pose a public health risk through drinking water exposure from the CCL universe solely because they lack health or occurrence data." EPA also received a recommendation for the agency to expand the use wastewater data and data collected under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). EPA will consider expanding its uses of wastewater data and data collected under FIFRA and TSCA for future CCL cycles.

EPA received comments requesting clarification on EPA's effort to combine the health data from multiple forms of some chemical contaminants when constructing the CCL 5 Chemical Universe. Another commenter had specific concerns about the chemical information sheets (CIS) for cypermethrin which included data for multiple isomers of the contaminant. In response to these comments, EPA has updated the Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5)—

Contaminant Information Sheet (USEPA, 2022c) for five contaminants to clarify which data entries are associated with which forms of the contaminant; these include cypermethrin, lithium, manganese, propiconazole, and vanadium.

b. Chemical Groups

EPA received many comments related to the inclusion of three contaminant groups on the CCL 5: cyanotoxins, disinfection byproducts (DBPs), and per- and polyfluoroalkyl substances (PFAS). Many commenters expressed support for listing these three groups on the CCL 5, while many were opposed or expressed concerns with the ways the groups were defined.

i. Cyanotoxins

EPA received comments supporting listing cyanotoxins as a group on the CCL 5. Supportive commenters noted the increase in frequency in harmful algal blooms (HABs) in drinking water sources, the widespread occurrence of cyanotoxins and often in complex mixtures, the harmful effects to humans and animals, and the challenges state drinking water treatment facilities face with water quality changes from HABs and removing cyanotoxins in a safe yet cost-effective way.

In contrast, EPA received a comment suggesting that EPA explain the rationale for retaining cyanotoxins on the CCL 5. The commenter pointed to the low occurrence results of the cyanotoxins monitored under UCMR 4. For EPA's rationale, see section III.C of this document.

ii. DBPs

EPA received comments supporting listing unregulated DBPs on CCL 5. One commenter specifically supported listing bromochloroacetic acids (BCAA) as one of the unregulated DBPs in the group, noting the contaminant causes abnormalities in laboratory animals and is commonly found in drinking water. Another supporting commenter of listing unregulated DBPs also recommends that EPA work to fill research gaps for these contaminants, because few DBPs have been quantitatively assessed for their occurrence and health effects. The commenter further states that occurrence and health effects as well as additional data on the accuracy and reliability of analytical methods for detecting unregulated DBPs would be beneficial as EPA considers revisions to the MDBP rule regulations.

A commenter asked the agency to provide justification on the lack of health effects and occurrence information for the DBPs listed on the CCL 5 and on the selection of the 23 DBPs from hundreds of known DBPs. The commenter also stated that EPA should present the supporting data for including DBPs as a group in the CCL, since there are marked differences in occurrence and health effects information among these DBPs. The commenter did agree with EPA's stated intent of evaluating DBPs in a coordinated manner to assure adequate disinfection. Many commenters supported EPA's decision that DBPs should be listed as a group and suggested DBPs should be considered for regulatory determination and/or under the efforts of the Microbial Disinfection Byproducts Rule revisions.

For CCL 5, the group of 23 unregulated DBPs includes the DBPs that were publicly nominated and/or in the top 250 scored CCL 5 Universe chemicals (outlined in Appendix P of the Final CCL 5 Chemical Technical Support Document). These DBPs bypassed the evaluation teams' review due to the ongoing EPA actions to consider revisions to five microbial and disinfection byproduct (MDBP) drinking water regulations in which EPA is also evaluating information on unregulated DBPs. Under the third Six-Year Review (SYR 3), EPA identified eight National Primary Drinking Water Regulations (NPDWRs) covered by five Microbial and Disinfection Byproducts (MDBP) rules as "candidates for revision" (USEPA, 2017). EPA is currently conducting analyses and consulting with the NDWAC to further evaluate these candidates and several unregulated DBPs for regulation under the potential revisions to the Microbial Disinfection Byproducts (MDBP) Rules. Additional information on the group of 23 unregulated DBPs on CCL 5 is included in Section 4.7 of the Final CCL 5 Chemical Technical Support Document.

iii. PFAS

Some comments supported listing chemicals as groups on the CCL 5 and in particular listing PFAS as a group. However, EPA received extensive comments opposing the Draft CCL 5 PFAS structural definition for being too narrow and excluding PFAS such as perfluoro-2-methoxyacetic acid (PFMOAA), detected in the Cape Fear River source water and drinking water. For the CCL 5, EPA maintains its decision that the PFAS group meets the criteria for listing, which is that they are not yet subject to drinking water regulation, are known or "anticipated" to occur in drinking water systems and may require drinking water regulation.

EPA's decision to retain the group of PFAS on CCL 5 also aligns with the agency's commitment to address PFAS, which was laid out in its October 2021 PFAS Strategic Roadmap (USEPA, 2021c).

EPÁ agrees with the commenters who recommended expanding the CCL 5 PFAS definition and in response, EPA is expanding the CCL 5 PFAS structural definition. For the CCL 5's PFAS structural definition, see section III.C of this document.

EPA's revised CCL 5 PFAS definition captures PFAS known to occur in drinking water and/or source water. Many of these were mentioned in the public comments, such as perfluoro-2methoxyacetic acid (PFMOAA) and perfluoro-2-methoxy propanoic acid (PMPA). The revised definition maintains the draft CCL 5 PFAS structural definition but augments it to include additional PFAS substructures such as PFAS that are ethers or highly branched, persistent in water, and known to occur in drinking water and/ or source water. This revised definition is only for the purposes of CCL 5. It is not meant to represent an agency-wide definition. The definition could be revised for future cycles as more information is gathered on PFAS. EPA includes additional language in this notice acknowledging emerging PFAS contaminants that EPA may consider moving directly to the regulatory determination process or consider listing those contaminants for future CCLs. The FRN also references EPA's Comptox Database which includes a CCL 5 PFAS list of over 10,000 PFAS substances that meet the Final CCL 5 PFAS definition.

c. Individual Chemical Contaminants

EPA received comments from multiple commenters regarding the listing status or information collected for individual contaminants listed on the Draft CCL 5. Some commenters expressed support for the listing of specific contaminants while others disagreed with EPA's evaluation and requested EPA reconsider listing specific contaminants on the Final CCL 5. EPA received comments pertaining to 1,4-dioxane, chlorpyrifos, cobalt, manganese, molybdenum, tungsten, and vanadium.

EPA received comments supporting the listing of 1,4-dioxane, chlorpyrifos, and manganese. Commenters cite the need for updated health assessments, concerns about new or existing health effects, occurrence, and use data, and potential benefits of Federal regulations for states as reasons for supporting the listing decision made by EPA.

EPA received comments requesting reevaluations of the listing decisions for cobalt, manganese, molybdenum, tungsten, and vanadium. Some commenters provided resources and analyses that they recommended EPA consider when listing a contaminant of interest. The recommendations provided by commenters frequently conflicted with established protocols and hierarchies that EPA applied uniformly across all chemical contaminants during the Classification step of CCL 5 described in Chapter 4 of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a). However, EPA will consider these recommendations and comments on the protocol's strengths and weaknesses when reviewing potential modifications for future CCL cycles. Additionally, some recommendations, though outside the scope of the CCL process, may be useful during the Regulatory Determination process.

EPA maintained the listing of 1,4-dioxane, chlorpyrifos, cobalt, manganese, molybdenum, tungsten, and vanadium on the Final CCL 5 because they are known or anticipated to occur in public water systems, may require drinking water regulations, and therefore meet the SDWA requirements for listing on the CCL. EPA has provided individual responses to each comment received for individual contaminants in the Response to Comments Document on the Draft Fifth Contaminant Candidate List (CCL 5) document.

3. The Microbial Process and Microbial Contaminants

EPA received a comment that neither the Draft CCL 5 FRN nor the CCL 5 Microbial Technical Support Document (Technical Support Document of the Draft Fifth Contaminant Candidate List—Microbial Contaminants) described the weight-of-evidence approach used when applying the modification made to the exclusionary screening criteria applied to screen the microbial universe to the PCCL. The modification expanded Criterion 9 of the screening criteria to include nosocomial pathogens where drinking water-related infections were implicated. The comment also stated that if EPA finalizes CCL 5 retaining the incorporation of this modified criterion, it must more clearly describe its approach to implementing the revised criterion given that nosocomial infections occur under a unique combination of exposure scenarios and involve individuals that are very susceptible to infection. EPA addresses this comment by clarifying in the Technical Support Document for the

Final Fifth Contaminant Candidate List (CCL 5)—Microbial Contaminants, the approach to implementing the revised criterion.

a. Comments on Individual Microbial Contaminants

EPA received comments on listing Legionella pneumophila and Mycobacterium. Two of the three commenters expressed support for listing the pathogen Legionella pneumophila on CCL 5, stating the burden *Legionella pneumophila* has on state drinking water programs. The third commenter recommended EPA address how the CCL 5 and MDBP rule revisions processes will interplay given the inclusion of the same contaminants, Legionella pneumophila, other pathogens, and DBPs being listed on CCL 5 as well as being considered in the MDBP rule revisions. EPA has listed Legionella pneumophila on CCL 5. The MDBP potential revisions are a separate agency action from CCL.

EPÅ received one comment supporting the inclusion of *Mycobacterium avium* and *Mycobacterium abscessus* on CCL 5 and supports not listing Non-tuberculous Mycobacteria (NTM) as a group on the CCL. EPA has listed speciated *Mycobacterium* on the CCL 5, versus as a group.

4. Contaminants Not on CCL 5

EPA received one comment to include two microbial contaminants, Hepatitis A and Salmonella enterica, on CCL 5. Hepatitis A and Salmonella enterica are not listed for CCL 5. Although both contaminants were listed on past CCLs, nominated for CCL 5, and still pose public health concerns, the outbreak data from CDC's NORS indicate that the route of exposure is not waterborne for the majority of infections.

5. Suggestions To Improve Future CCLs

EPA received a comment to consider presenting CCL 5, and future CCLs, as an organized list that illustrates relative levels of potential risk and the gaps in information needed to craft risk management decisions. EPA does not organize CCLs based on "relative levels of potential risk" or "gaps needed to craft risk management decisions' because both of these actions require analysis and evaluation that is outside the scope of SDWA requirements for the CCL and align with the regulatory determinations and rule development process. However, EPA provides a table (Exhibit 4) in the FRN that shows the best available occurrence and health effects data for contaminants listed on CCL 5. Another commenter

recommends that future CCLs be reviewed by an external expert panel in advance of the proposal. The commenter noted EPA prepared the Draft CCL 5 **Federal Register** notice without seeking external expert review as was recommended by NDWAC and has been past practice (e.g., CCLs 1 and 3). EPA will consider the use of an external expert panel for future CCLs.

The commenter notes the technical support documents do not describe any internal process control measures, making the role of an independent third-party review even more important. EPA includes a description of the data management and quality assurance steps taken for the chemical CCL 5 process in Chapter 6 of the CCL 5 Final Chemical Technical Support Document (USEPA, 2022a).

B. Recommendations From the EPA Science Advisory Board

On January 11, 2022, EPA held the first of five public meetings with the Science Advisory Board (SAB) Drinking Water Committee (DWC) Augmented for the CCL 5 review. During this initial meeting, EPA provided an overview of the process used to develop the Draft CCL 5 and answered questions from the Committee. EPA then requested Committee members to review the Draft CCL 5 materials and address the following charge questions:

1. Please comment on whether the **Federal Register** notice and associated support documents are clear and transparent in presenting the approach used to list contaminants on the Draft CCL 5. If not, please provide suggestions on how EPA could improve the clarity and transparency of the FRN and the support documents.

2. Please comment on the process used to derive the Draft CCL 5, including but not limited to, the CCL 5 improvements to assess potential drinking water exposure, consider sensitive populations, and prioritize contaminants that represent the greatest potential public health concern.

3. Based on your expertise and experience, are there any contaminants currently on the Draft CCL 5 that should not be listed? Please provide peerreviewed information or data to support your conclusion.

4. Based on your expertise and experience, are there any contaminants which are currently not on the Draft CCL 5 that should be listed? Please provide peer-reviewed information or data to support your conclusion.

On February 16 and February 18, 2022, EPA reconvened with the SAB DWC to discuss preliminary responses to the charge questions and answer remaining questions. The Committee met again on June 6, 2022 to discuss a draft of the final report, and again on July 18, 2022 to discuss their recommendations for CCL 5 with the Chartered SAB. The SAB's final recommendations were provided in their report "Review of the EPA's Draft Fifth Drinking Water Contaminant Candidate List (CCL 5)" (USEPA, 2022e) to the EPA Administrator on August 19, 2022.

1. Overall SAB Recommendations

The SAB commended EPA on the level of effort in developing the Draft CCL 5 and support documents. Overall, the SAB found the CCL 5 development process and documentation clear and transparent. The SAB provided many recommendations in response to EPA's charge questions and emphasized the following "key" recommendations for CCL 5 and future CCLs to the Administrator.

• The SAB recommended that the EPA clarify the types of occurrence data that were included or rejected for consideration in development of the Draft CCL 5. In particular, clarifying how the literature review of the chemical contaminants in the Preliminary Contaminant Candidate List (PCCL) was conducted and used. Specifically, the SAB recommended providing an explicit list of the criteria used to screen chemical contaminants from the initial universe to form the PCCL before the point-based scoring is applied. The SAB suggested EPA explain the rationale for setting the threshold for the number of chemicals to be included on the Draft CCL 5 at

EPA response: In response to SAB's recommendation, the agency added clarification of how the occurrence literature review was conducted for the chemical process is described in Appendix E, Protocol of the Literature, of the Final CCL 5 Chemical Technical Support Document (2022a). The occurrence data that was considered for chemical contaminants can be found in the Appendix N, Data Management for CCL 5, of the Final CCL 5 Chemical Technical Support Document (2022a). Appendix N details the primary data sources that were considered for chemical contaminants. The information identified through the literature search was used to fill data gaps and provide additional information most relevant to drinking water exposure. This information was provided on the chemical CIS for the evaluators to consider when making their listing recommendations.

For past CCLs, EPA has received many comments about CCLs consisting of too many contaminants. With over 20,000 chemicals in the CCL 5 Universe and in response to past feedback, EPA used the screening scores to select and advance the top 250th scored chemicals for evaluation teams to review for potential inclusion on the CCL 5. Limiting the PCCL 5 to the top 250th scored chemicals, plus 53 nominated chemicals that were not already included in the top scored chemicals, focuses EPA's resources on those contaminants with sufficient data to evaluate whether they are known, or anticipated to occur in public water systems and those that pose the greatest potential public health concern. EPA conducted statistical analyses and developed a logistic regression model to validate selection of the top 250th scored chemicals for the PCCL 5. The results of those analyses are in Section 4.6 of the Final CCL 5 Chemical Technical Support document (USEPA, 2022a).

 The SAB supported the use of contaminant groups being listed on the CCL, but recommended transparency about the reasoning for listing contaminants as a group, and clarifying whether individual contaminants or subgroups within the groups should be prioritized. SAB also recommended EPA provide information on the criteria for grouping individual per- and polyfluoroalkyl substances (PFAS) and disinfection byproducts (DBPs) within the CCL 5. The SAB also recommended clarifying the justification for inclusion of cyanotoxins as a group despite relatively low occurrence data in the UCMR 4. In addition, the SAB recommended EPA elaborate on how listing contaminants as groups impacts the regulatory process.

EPĀ response: In response to SAB's recommendations, EPA has provided additional rationale for listing contaminants as groups on CCL 5 in Section III.C of this document. The objective of CCL is to identify priority contaminants for potential regulation. As described in Section III.C. of this document and also described in Section 4.7 of the Final CCL 5 Chemical Technical Support Document, cyanotoxins, DBPs, and PFAS are chemical groups that have already been identified as agency priorities and contaminants of concern for drinking water under other agency actions, including the 2015 Algal Toxin Risk Assessment and Management Strategic Plan for Drinking Water, EPA's decision to identify a number of microbial and disinfection byproducts (MDBPs) drinking water regulations as candidates for revision in the third Six-Year Review (SYR 3) of the NPDWRs, and the 2021 PFAS Strategic Roadmap.

EPA is listing cyanotoxins on CCL 5 as an aggregate group in order to encompass all toxins produced by cyanobacteria. For EPA's rationale see section III.C of this document.

As information is available, EPA will evaluate the scientific data on the listed groups, including evaluating subgroups and/or individual contaminants within the groups to inform any regulatory determinations for the group, subgroup, or individual contaminants in the group.

• The SAB suggested that EPA elaborate on how sensitive populations were evaluated for chemical contaminant risks, clarify why immunosuppressed individuals are not considered sensitive populations and specify terminology regarding chronic disease and serious illness as risk factors when assessing microbial contaminant risks.

EPA response: As described in Final CCL 5 Chemical Technical Support Document section 4.3.1, sensitive populations were evaluated based on calculating health concentrations. For carcinogens, the health concentration is the one-in-a-million (10⁻⁶) cancer risk expressed as a drinking water concentration. EPA applied agedependent adjustment factors (ADAFs) to chemicals identified as having a mutagenic mode of action to account for risks associated with early life exposure to mutagenic carcinogens. For noncarcinogens, the toxicity value (RfD or equivalent) was divided by an exposure factor (i.e., body weight-adjusted drinking water intake; USÉPA, 2019) relevant to the target population and critical effect and multiplied by a 20% relative source contribution (USEPA, 2000b). Target populations considered for CCL 5 include sensitive subpopulations such as bottle-fed infants, pregnant women, and lactating women. If a chemical has toxicity values based on both cancer and non-cancer data, EPA selected the endpoint that resulted in the most health protective value as the final health concentration.

As described in the FRN for the Draft CCL 5, EPA states "The SDWA refers to several categories of sensitive populations including children and infants, elderly, pregnant women, and persons with a history of serious illness." Additionally, in the FRN for Draft CCL 5, EPA states "health effects for individuals with marked immunosuppression (e.g., primary or acquired severe immunodeficiency, transplant recipients, individuals undergoing potent cytoreductive

treatments) are not included in this health effect scoring. While such populations are considered sensitive subpopulations, immunosuppressed individuals often have a higher standard of ongoing health care and protection required than the other sensitive populations under medical care. More importantly, nearly all pathogens have very high health effect scores for the markedly immunosuppressed individuals; therefore, there is little differentiation between pathogens based on health effects for the immunosuppressed subpopulation." EPA clarifies that the Agency does view immunocompromised individuals as a sensitive population, and immunocompromised populations are considered regardless of marked suppression of immune system and/or quality of health care when weighing health risks and when scoring the microbes' severity for CCL. See the Final CCL 5 Microbial Technical Support Document CIS sheets for supporting information. EPA has clarified the terms "chronic disease" and "serious illness" in the Final CCL 5 Microbial Technical Support Document (USEPA, 2022b).

• The SAB recommended EPA provide clarification of the difference in approach used by the chemical and microbial processes in regard to weighing expert opinion on contaminants to be included on the CCL 5

EPA response: For CCL 5, the microbial process relied on expert opinion for inclusion of contaminants on the CCL 5 due to the composite scores of the microbial PCCL 5 contaminants varying slightly (i.e., 0.1 difference) of each other and having no natural break in scores, as was the case with CCL 3 and CCL 4. To ensure CCL 5 was capturing the microbial contaminants with the greatest public health risk, EPA consulted with CDC microbial experts. For the CCL 5 chemical process, EPA relied on two evaluation teams, internal subject matter experts, to evaluate 214 PCCL 5 chemicals and provide listing recommendations for CCL 5.

• The SAB recommended expanding the CCL 5 definition of PFAS to be more inclusive of a broad range of compounds of potential health risk, recommending a definition that captures all relevant fluorinated compounds and degradates in commercial use or entering the environment.

EPA response: EPA revised the CCL 5 PFAS definition to be more inclusive. This revised definition maintains the Draft CCL 5 structural definition but is augmented to include additional PFAS substructures to address PFAS known to occur in drinking water and/or source water, such as Perfluoro-2-methoxyacetic acid (PFMOAA) and Perfluoro-2-methoxy propanoic acid (PMPA). This revised definition is only for the purposes of CCL 5. It is not meant to represent an agency-wide definition. The definition could be revised for future cycles as more information is gathered on PFAS. For more information on the CCL 5 PFAS group and structural definition, see Section IV.A.2.b.iii of this document.

 The SAB suggested that the definition and discussion of waterborne disease outbreaks (WBDO) as a criterion for microbial contaminant selection be expanded and relocated to earlier in the final FRN. The SAB further clarified that the discussion about WBDOs should include a clear outline of the definition, the limitations associated with the underlying data, how the data were used in the selection process, and how sensitive populations were considered. The SAB also recommended renaming "health effects" to "health risks" throughout the CCL 5 documents for both microbial and chemical contaminants.

EPA response: In the Final CCL 5 Microbial Technical Support Document, EPA defines WBDOs, and further clarifies how WBDO data are used in the selection process, and how sensitive populations were considered for microbial contaminants. EPA acknowledges there are limitations to the use of WBDO outbreak data and has expanded the discussion of WBDO criteria to include the limitations associated with WBDO data in the Final CCL 5 Microbial Technical Support Document (USEPA, 2022b).

EPA agrees that the term "health risk" rather than "health effects" is a more appropriate term to use in some instances. EPA considers risk to be the chance of harmful effects to human health or to ecological systems resulting from exposure to an environmental stressor (USEPA, 2022f). An endpoint may be associated with a risk of a disease which is determined after evaluating the health effects, occurrence, and potential exposure data. There are instances in the CCL 5 process when EPA identifies an adverse health endpoint (or effect) from a health assessment but does not go further to analyze the risk of disease in humans and therefore the term "health effects" is appropriate. EPA has reviewed the use of the terms throughout the CCL 5 documents and made the appropriate

• The SAB recommended including additional bisphenols, bisphenol F (BPF) and bisphenol S (BPS) on the

Final CCL 5. In addition to saxitoxin (STX), the EPA should include other saxitoxins including neo-STX and dc-STX on the Final CCL.

EPA response: EPA reviewed the references provided by the SAB to support their recommendations for including Bisphenol S and F on CCL 5. However, there are still substantial health effects and occurrence data gaps for Bisphenol S and Bisphenol F to determine whether they are known, or anticipated to occur in public water systems and pose the greatest potential public health concern. Therefore, EPA is not listing them at this time. EPA will consider additional Bisphenols for future CCLs.

Cyanotoxins is listed as a group on CCL 5. The group of cyanotoxins on CCL 5 includes, but is not limited to: Anatoxin-a, cylindrospermopsin, microcystins, and saxitoxin. As information is available, EPA will evaluate scientific data on the listed groups, subgroups, and/or individual contaminants included in the group to inform any regulatory determinations for the group, subgroup, or individual contaminants in the group.

• The SAB questioned how microbial organisms covered under existing regulations were listed on the CCL, for example *Legionella* and viruses covered by the Surface Water Treatment Rules (SWTRs) and Ground Water Rule (GWR). The SAB recommended that the EPA provide greater clarity on the process used to establish the list of microbial contaminants, as well as a rationale for carrying over most of the microbial contaminants from prior CCLs.

EPA response: Despite the MCLGs for Legionella and for viruses, these contaminants have limitations as a class under the SWTRs and GWR, and therefore lack contaminant-specific monitoring and filtration or treatment requirements. Because Legionella and viruses have known public health risks associated in water systems and do not have specific regulatory requirements, EPA believes it is appropriate to list these as unregulated contaminants for purposes of inclusion on the CCL.

For clarification, the microbial contaminants listed on CCL 5 that were listed on prior CCLs were not "carried-over"; these contaminants did not receive positive determinations through the regulatory determination process, and therefore are placed back into the microbial universe. After evaluating these contaminants through the CCL microbial process, their composite scores consisting of health effects and occurrence data supported listing them for CCL 5. EPA has provided additional

clarity on the process and justification for each microbial contaminant included on the Final CCL 5 Microbial Technical Support Document (USEPA, 2022b).

 The SAB suggested providing a table containing the considered PFAS, similar to the table for DBPs.

EPA response: EPA is providing a list of PFAS chemicals included in the CCL 5 PFAS group (WATER|EPA: Chemical Contaminants—CCL 5 PFAS subset) on the EPA's CompTox Dashboard website under List of Chemicals (https://comptox.epa.gov/dashboard/chemicallists).

• The SAB suggested that EPA consider grouping other compounds, such as organophosphate esters and triazines.

EPA response: EPA will take this recommendation into consideration for future CCLs.

• The SAB advised EPA to ensure that the CCL 5 microbial process incorporates the most up-to-date version of the Control of Communicable Diseases Manual.

EPA response: EPA used the most upto-date version of the Manual of Clinical Microbiology (MCM) and where the Control of Communicable Disease Manual is cited, a newer citation from either the MCM or CDC is also cited. EPA will ensure the most up-to-date version of the Control of Communicable Diseases Manual be used in future CCLs.

• The SAB proposed that EPA clarify the process of selecting contaminants for monitoring under the UCMR when contaminants had *only* health effects or occurrence data.

EPA response: For each UCMR cycle, the UCMR program coordinates with the CCL program in establishing the list of contaminants for monitoring. UCMR considers contaminants listed on the CCL, other priority contaminants, and the opportunity to use multicontaminant methods to collect occurrence data in an efficient, costeffective manner.

EPA evaluates candidate UCMR contaminants using a multi-step prioritization process. The first step includes identifying contaminants that: (1) were not monitored under prior UCMR cycles; (2) may occur in drinking water; and (3) are expected to have a completed, validated drinking water analytical method in time for rule proposal. The next step considers the following: availability of health assessments or other health-effects information (e.g., critical health endpoints suggesting carcinogenicity); public interest (e.g., PFAS); active use (e.g., pesticides that are registered for use); and availability of occurrence data. EPA also considers stakeholder input; looks at the cost-effectiveness of the potential monitoring approaches; considers implementation factors (e.g., laboratory capacity); and further evaluates health effects, occurrence, and persistence/mobility data.

• The SAB recommended that EPA further describe the validity of the health effects linear scoring system for

microbial contaminants.

EPA response: When the CCL microbial process was developed, it was recognized that pathogens may produce a range of illnesses, from asymptomatic infection to fulminate illness progressing rapidly to death. The health effect protocol scores are representative of common clinical presentation for specific pathogens for the population category under consideration. EPA believes the linear scoring system enables the reproducibility of the scores for health risks.

 The SAB suggested clarifying the reasons for calculating the Pathogen Total Score for microbial contaminants.

EPA response: EPA uses the composite pathogen score, which factors in the microbe's three attribute scoring protocols for occurrence, waterborne disease outbreaks, and health effects to score and the rank contaminants on the PCCL. The composite score normalizes the health effects (for the general population and for sensitive populations) and occurrence because the agency believes they are of equal importance. This scoring system also prioritizes and restricts the number of pathogens on the CCL to those that are strongly associated with water-related diseases.

• SAB recommended EPA clarify the reason for using a 10-year timeframe for the supplemental literature review for the chemical contaminants' occurrence data.

EPA response: For CCL 5, EPA's goal was to conduct a targeted occurrence literature search for the chemical contaminants to identify supplemental data that would be more recent or provide more information on potential exposure from drinking water than information from primary data sources used to compile the CCL 5 Universe. For future CCLs, EPA will consider expanding the timeframe for occurrence literature searches for chemical contaminants.

• The SAB suggested that EPA compare the CCL 5 list to the European-based data to identify overlooked compounds of high concern.

EPA response: For CCL 5, EPA incorporated the use of several European data sources in the CCL 5 process. Appendix B of the Final CCL 5

Chemical Technical Support Document (USEPA, 2022a) list those data sources that were used as supplemental sources for CCL 5. For example, EPA searched for toxicity values such as derived no effect levels (DNELs) from European Chemicals Agency (ECHA) Registration Dossiers to derive CCL Screening Levels for chemicals of interest.

• The SAB recommended that EPA incorporate speciation information into the scoring system to aid in the justification for inclusion or exclusion of Vanadium in the Final CCL.

EPA response: Based upon the data collected for CCL 5, including occurrence data collected for UCMR 3 and the available health assessments, EPA concludes that vanadium is known or anticipated to occur in public water systems and may require drinking water regulation and therefore meets the criteria for listing under the SDWA. EPA recognizes the value of data on vanadium speciation, both in terms of potential differences in health effects resulting from oral exposures and occurrence in water from public systems. EPA is aware that the National Toxicology Program (NTP) is currently conducting toxicity studies on vanadyl sulfate (+4) and sodium metavanadate (+5) to fill data gaps. When NTP publishes their subchronic study results, it will contribute to the vanadium health effects database to be considered for the Regulatory Determination Process and/or future CCL cycles.

• The SAB recommended removing Shigella sonnei, Campylobacter and Helicobacter pylori from the Final CCL 5. In addition, before finalizing CCL 5, the SAB also suggested that EPA conduct further evaluation of caliciviruses and provide further justification for including enteroviruses and Human Adenovirus on CCL 5.

EPA response: Shigella sonnei, Campylobacter jejuni, caliciviruses, enteroviruses, and adenovirus remain a concern for vulnerable water systems such as undisinfected (i.e., undisinfected ground water systems) or inadequately disinfected systems. EPA has provided additional supporting evidence and justification of inclusion of each microbial organism on the CCL 5 in the Final CCL 5 Microbial Technical Support Document.

• The SAB recommended that EPA clearly communicate the relative levels of potential risk and gaps in information needed to craft risk management decisions for PFAS.

EPA response: The SDWA requires EPA to follow a process to identify unregulated contaminants for potential regulation. The CCL is one of the many integral components of EPA's coordinated risk management process. The objective of CCL is to identify contaminants of concern in drinking water to inform and assist in priority-setting efforts for potential regulatory determination. The process of Regulatory Determination examines in depth if there is sufficient data for EPA to make a decision on whether EPA should initiate a rulemaking process to develop an NPDWR for a specific contaminant.

2. Recommendations for Future CCLs

For future CCLs, the SAB suggested that EPA bring the processes for selecting the chemical contaminants and the microbial contaminants into better alignment with each other, noting that currently the two processes differ in detail and technique. ÉPA recognizes the differences between the chemical and microbial processes due to differing metrics and data availability for contaminant assessment. Although the chemical and microbial processes differ, the overarching steps of the CCL process of building the universe, screening, and classification of contaminants are followed in parallel. However, for future CCLs, EPA will re-examine both the chemical and microbial processes to determine if there are benefits to aligning the two processes.

Specifically, for the CCL chemical process, the SAB recommended future CCLs consider evaluating contaminants such as: shorter lived pesticides that transform into longer-lived metabolites or degradates, urban runoff occurrence data in parallel with wastewater occurrence data, assess data gathered in Europe during the implementation of the REACH system, the NORMAN network, and IP-CHEM databases to assess contaminants in surface or drinking water, identify and assess byproducts, impurities, and transformation products (including metabolites and degradates), persistent and mobile organic compounds (PMOCs), antimicrobials, microplastics, nanoparticles, and weigh whether to include manganese and tungsten on future CCLs.

To improve the CCL chemical processes, the SAB suggested the following for future CCLs: consider employing machine learning to identify whether there may be other compounds of concern within the baseline of compounds, report the range and median method detection limit and reporting limit for each occurrence dataset listed in the CIS and using this information to inform the prevalence score for chemical contaminants, ensure that data cited in secondary sources are

from qualifying primary sources, observe anticipated speciation of metals in drinking water and potential source waters including groundwater. In addition, the SAB recommended that EPA develop a strategy to address the gap in occurrence data that will arise when the U.S. Geological Survey (USGS) discontinues its contaminants monitoring program.

For future CCLs EPA will consider evaluating the data sources that the SAB referenced for the groups of contaminants in their CCL 5 recommendations, including additional European-based data sources, to determine if those sources are appropriate to use as primary data sources when developing the chemical universe or supplemental data sources when filling data gaps for future CCLs. EPA will also consider evaluating the contaminants SAB has referenced. In addition, EPA will reconsider the use of machine learning in the future rounds of CCL. Also, EPA intends to continue to use the USGS compiled for CCL 5 for future CCLs but will consider other strategies to address the gap in occurrence data that will arise when the USGS ends its contaminant monitoring program.

For the microbial process, the SAB suggested future CCLs consider adding a group of pathogenic mycobacteria to focus research and public health protection on a more identifiable and actionable group of opportunistic pathogens in comparison to the nondescript NTM designation. EPA will take this recommendation into consideration for future CCLs.

3. EPA's Overall Response to SAB Recommendations

EPA has considered all SAB's comments and incorporated recommendations, where applicable, for the Final CCL 5 to increase the scientific concepts, clarity, and transparency of the decisions relative to the contaminants included on CCL 5. These updates/changes are reflected in the Final CCL 5 Chemical and Microbial Technical Support Documents (USEPA, 2022a and USEPA, 2022b, respectively). Other recommendations made by SAB in their final report (2022e) will be considered for future CCLs.

V. Data Availability for CCL 5 Contaminants

In an effort to provide current data availability of the CCL 5 contaminants

with respect to occurrence and health effects data and EPA approved analytical methods, EPA has provided a summary table in Exhibit 4, depicting the CCL 5 chemicals categorized into five groups depending upon the availability of their occurrence data and peer-reviewed health assessment(s) containing oral toxicity values at the time of the Draft CCL 5 publication. The status of health effects data availability for the CCL chemical contaminants, as of the date by which each chemical was evaluated for placement on the Draft CCL 5 (February to July 2020) and for analytical methods (September 2020) is presented in Exhibit 4.

For individual chemicals of the cyanotoxins, DBPs and PFAS groups, the availability of health effects and occurrence data varies with individual chemicals in each group. The agency is addressing these groups broadly, instead of individually, in drinking water based on a subset of chemicals in these groups that are known to occur in public water systems and may cause adverse health effects.

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Exhibit 4—Data Availability/Information for the CCL 5 Contaminants

CASRN	DTXSID	Common name	Best Available Occurrence Data	Is a Health Assessment Available?	Is an Analytical Method Available?		
A. Contamin	A. Contaminants with Nationally Representative Finished Water Occurrence Data and Qualifying Health Assessments						
96-18-4	DTXSID9021390	1,2,3-Trichloropropane	National Finished Water	Yes	Yes		
123-91-1	DTXSID4020533	1,4-Dioxane	National Finished Water	Yes	Yes		
95-53-4	DTXSID1026164	2-Aminotoluene	National Finished Water	Yes	Yes		
51-28-5	DTXSID0020523	2,4-Dinitrophenol	National Finished Water	Yes	Yes		
319-84-6	DTXSID2020684	alpha- Hexachlorocyclohexane	National Finished Water	Yes	Yes		
7440-42-8	DTXSID3023922	Boron	National Finished Water	Yes	Yes		
63-25-2	DTXSID9020247	Carbaryl	National Finished Water	Yes	Yes		
2921-88-2	DTXSID4020458	Chlorpyrifos	National Finished Water	Yes	Yes		
7440-48-4	DTXSID1031040	Cobalt	National Finished Water	Yes	Yes		
60-57-1	DTXSID9020453	Dieldrin	National Finished Water	Yes	Yes		
330-54-2	DTXSID0020446	Diuron	National Finished Water	Yes	Yes		
13194-84-4	DTXSID4032611	Ethoprop	National Finished Water	Yes	Yes		
7439-93-2	DTXSID5036761	Lithium	National Finished Water	Yes	Yes		
7439-96-5	DTXSID2024169	Manganese	National Finished Water	Yes	Yes		
7439-98-7	DTXSID1024207	Molybdenum	National Finished Water	Yes	Yes		

CASRN	DTXSID	Common name	Best Available Occurrence Data	Is a Health Assessment Available?	Is an Analytical Method Available?
42874-03-3	DTXSID7024241	Oxyfluorfen	National Finished Water	Yes	Yes
52645-53-1	DTXSID8022292	Permethrin	National Finished Water	Yes	Yes
41198-08-7	DTXSID3032464	Profenofos	National Finished Water	Yes	Yes
1918-16-7	DTXSID4024274	Propachlor	National Finished Water	Yes	Yes
91-22-5	DTXSID1021798	Quinoline	National Finished Water	Yes	Yes
107534-96- 3	DTXSID9032113	Tebuconazole	National Finished Water	Yes	Yes
78-48-8	DTXSID1024174	Tribufos	National Finished Water	Yes	Yes
7440-62-2	DTXSID2040282	Vanadium	National Finished Water	Yes	Yes
B. Contamin Assessments	ants with Non-Nationa	Illy Representative Finished	Water Occurrence Data a	nd Qualifying H	lealth
2163-68-0	DTXSID6037807	2-Hydroxyatrazine	Non-National Finished Water	Yes	No
1689-84-5	DTXSID3022162	Bromoxynil	Non-National Finished Water	Yes	No
10605-21-7	DTXSID4024729	Carbendazim (MBC)	Non-National Finished Water	Yes	No
141-66-2	DTXSID9023914	Dicrotophos	Non-National Finished Water	Yes	Yes
55283-68	DTXSID8032386	Ethalfluralin	Non-National Finished Water	Yes	No
120068-37-	DTXSID4034609	Fipronil	Non-National Finished Water	Yes	No
2164-17-2	DTXSID8020628	Fluometuron	Non-National Finished Water	Yes	Yes
36734-19-7	DTXSID3024154	Iprodione	Non-National Finished Water	Yes	No
121-74-5	DTXSID4020791	Malathion	Non-National Finished Water	Yes	Yes
27314-13	DTXSID8024234	Norflurazon	Non-National Finished Water	Yes	Yes
298-02-2	DTXSID4032459	Phorate	Non-National Finished Water	Yes	Yes
732-11-6	DTXSID5024261	Phosmet	Non-National Finished Water	Yes	No
709-98-8	DTXSID8022111	Propanil	Non-National Finished Water	Yes	Yes

CASRN	DTXSID	Common name	Best Available Occurrence Data	Is a Health Assessment Available?	Is an Analytical Method Available?
2312-35-8	DTXSID4024276	Propargite	Non-National Finished Water	Yes	No
139-40-2	DTXSID3021196	Propazine	Non-National Finished Water	Yes	Yes
114-26-1	DTXSID7021948	Propoxur	Non-National Finished Water	Yes	Yes
96182-53-5	DTXSID1032482	Tebupirimfos	Non-National Finished Water	Yes	No
153719-23- 4	DTXSID2034962	Thiamethoxam	Non-National Finished Water	Yes	No
2303-17-5	DTXSID5024344	Tri-allate	Non-National Finished Water	Yes	No
C. Contamin	ant with Nationally Re	presentative Finished Wate	r Occurrence Data Lackin	g Qualifying He	alth Assessments
57-63-6	DTXSID5020576	17-alpha ethynyl estradiol	National Finished Water	No	Yes
1634-04-4	DTXSID3020833	Methyl tert-butyl ether (MTBE)	National Finished Water	No	Yes
D. Contamin	ants with Qualifying H	lealth Assessments Lacking	Finished Water Occurren	ce Data	
3397-62-4	DTXSID1037806	6-Chloro-1,3,5-triazine- 2,4-diamine	National Ambient Water	Yes	Yes
30560-19-1	DTXSID8023846	Acephate	National Ambient Water	Yes	Yes
107-02-8	DTXSID5020023	Acrolein	National Ambient Water	Yes	No
84-65-1	DTXSID3020095	Anthraquinone	National Ambient Water	Yes	No
741-58-2	DTXSID9032329	Bensulide	Non-national Ambient Water	Yes	Yes
80-05-7	DTXSID7020182	Bisphenol A	National Ambient Water	Yes	No
143-50-0	DTXSID1020770	Chlordecone (Kepone)	Non-national Ambient Water	Yes	Yes
6190-65-4	DTXSID5037494	Deethylatrazine	National Ambient Water	Yes	No
1007-28-9	DTXSID0037495	Desisopropyl atrazine	National Ambient Water	Yes	Yes
333-41-5	DTXSID9020407	Diazinon	National Ambient Water	Yes	Yes
60-51-5	DTXSID7020479	Dimethoate	National Ambient Water	Yes	Yes
142459-58- 3	DTXSID2032552	Flufenacet (Thiaflumide)	National Ambient Water	Yes	No

CASRN	DTXSID	Common name	Best Available Occurrence Data	Is a Health Assessment Available?	Is an Analytical Method Available?
16752-77-5	DTXSID1022267	Methomyl	Non-National Finished Water	Yes	Yes
22967-92-6	DTXSID9024198	Methylmercury	National Ambient Water	Yes	No
13071-79-9	DTXSID2022254	Terbufos	National Ambient Water	Yes	Yes
126-73-8	DTXSID3021986	Tributyl phosphate	National Ambient Water	Yes	No
95-63-6	DTXSID6021402	Trimethylbenzene (1,2,4-)	National Ambient Water	Yes	Yes
115-96-8	DTXSID5021411	Tris(2-chloroethyl) phosphate (TCEP)	National Ambient Water	Yes	No
7440-33-7	DTXSID8052481	Tungsten	National Ambient Water	Yes	No
E. Contamin	ants Lacking National	ly Representative Finished	Water Occurrence Data an	d Qualifying Ho	ealth Assessments
93413-62-8	DTXSID40869118	Desvenlafaxine	Non-National Finished Water	No	No
86386-73-4	DTXSID3020627	Fluconazole	Non-National Finished Water	No	No
104-40-5	DTXSID3021857	Nonylphenol	Non-National Finished Water	No	Method in review

Key to Exhibit

National = Occurrence data that are nationally representative are available Non-National = Occurrence data that are not nationally representative are available Note: Data availability was not assessed for cyanotoxins, DBPs and PFAS.

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As shown in Exhibit 4, Group A are contaminants that have nationally representative finished drinking water data and a peer reviewed health assessment deriving an oral toxicity value and are likely to have sufficient data available to be placed on a short list for further assessment under RD 5. The contaminants in Group B have finished drinking water data that is not nationally representative and peer reviewed health assessments. Group B contaminants may have sufficient data to be placed on a short list for further assessment under RD 5, particularly if the non-nationally representative occurrence data shows detections at levels of public health concern. Contaminants in groups C, D, and E of Exhibit 4 are those that lack either a peer reviewed health assessment or finished water data have more substantial data needs and are unlikely to have sufficient information to allow

further assessment under RD 5. For Groups C, D, and E, EPA plans to identify them as research priorities and work to fill their research needs such as evaluating the potential for monitoring under the UCMR program or identifying those contaminants as priorities for health effects research. In addition, EPA assessed the data availability of the PCCL 5 chemicals that are not included on CCL 5. For more information on EPA methodology to identify data availability and summary tables, see Chapter 5 of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a).

The SAB and other commenters have recommended additional prioritization of the CCL 5 contaminants to communicate research needs, help focus efforts for researchers, and inform future regulatory decision-making. EPA acknowledges that multiple contaminants on the CCL 5 have substantial data and information needs

to fulfill in order for the agency to make a regulatory determination in accordance with SDWA 1412 (b)(1)(A). By identifying those contaminants that need additional research and information, EPA is communicating to stakeholders both research priorities and gaps for these contaminants.

VI. Next Steps and Future Contaminant Candidate Lists

The CCL process is critical to shaping the future direction of drinking water regulations. The agency will continue to examine relevant research studies and gather additional data to prioritize CCL 5 contaminants to make regulatory determinations on at least five contaminants for Regulatory Determination 5. The agency will also continue to refine the CCL process, gather and examine the best available data, and identify contaminants for the CCL 6. EPA expects to complete the CCL 6 in late 2026.

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Radhika Fox.

Assistant Administrator.

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR 296

[Docket ID FEMA-2022-0037]

RIN 1660-AB14

Hermit's Peak/Calf Canyon Fire Assistance

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Interim final rule; request for comments.

SUMMARY: This interim final rule sets out the procedures for Claimants to seek compensation for injury or loss of property resulting from the Hermit's Peak/Calf Canyon Fire.

DATES:

Effective Date: This rule is effective November 14, 2022.

Comment Date: Comments must be received on or before January 13, 2023.

ADDRESSES: You may submit comments, identified by Docket ID FEMA–2022–0037, via the Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

FOR FURTHER INFORMATION CONTACT:

Angela Gladwell, Office of Response and Recovery, 202–646–3642, FEMA-Hermits-Peak@fema.dhs.gov. Persons with hearing or speech challenges may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested persons are invited to participate in this rulemaking by submitting comments and related materials. We will consider all comments and material received during the comment period.

If you submit a comment, include the Docket ID FEMA–2022–0037, indicate the specific section of this document to which each comment applies, and give the reason for each comment. All submissions may be posted, without change, to the Federal e-Rulemaking Portal at http://www.regulations.gov, and will include any personal information you provide. Therefore, submitting this information makes it public.

Viewing comments and documents: For access to the docket, to read background documents or comments received, go to the Federal e-Rulemaking Portal at http://www.regulations.gov.

FEMA will hold four in-person public meetings to solicit public feedback about this Interim Final Rule. FEMA is announcing these public meetings to give the public as much notice as possible regarding their dates. FEMA will hold meetings on the below dates. If the locations and times of these meetings change, FEMA will announce the specific times and locations in a separate Federal Register document.

November 17, 2022 from 5:00 p.m. to 7:00 p.m. MT at Old Memorial Middle School, 947 Legion Drive, Las Vegas, NM 87701;

December 1, 2022 from 5:00 p.m. to 7:00 p.m. MT at the Mora High School, 10 Ranger Road, Mora, NM 87732;

December 15, 2022 from 5:00 p.m. to 7:00 p.m. MT at Old Memorial Middle School, 947 Legion Drive, Las Vegas, NM 87701; and

January 5, 2023 from 5:00 p.m. to 7:00 p.m. MT at the Mora High School, 10 Ranger Road, Mora, NM 87732.

Depending on the number of speakers, the meetings may end before their announced end time, following the last call for comments. Reasonable accommodations are available for people with disabilities. To request a reasonable accommodation, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section as soon as

possible. Last minute requests will be accepted but may not be possible to fulfill. All comments on this IFR made during the meetings will be posted to https://www.regulations.gov, Docket ID FEMA-2022-0037. Please review http://www.fema.gov/hermits-peak for more information and any updates on these public meetings.

II. Background

On September 30, 2022, President Biden signed into law the Hermit's Peak/Calf Canyon Fire Assistance Act ("Act") as part of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023, Public Law 117–180, 136 Stat. 2114 (2022). The Congress passed the Act to compensate those parties who suffered injury and loss of property from the Hermit's Peak/Calf Canyon Fire ("Fire").

On April 6, 2022, the U.S. Forest Service initiated the Las Dispensas-Gallinas prescribed burn on Federal land in the Santa Fe National Forest in San Miguel County, New Mexico. That same day the prescribed burn, which became known as the "Hermit's Peak Fire," exceeded the containment capabilities of the U.S. Forest Service and was declared a wildfire, spreading to other Federal and non-Federal lands.1 On April 19, 2022, the Calf Canyon Fire, also in San Miguel County, New Mexico, began burning on Federal land and was later identified as the result of a pile burn in January 2022 that remained dormant under the surface before reemerging.² The Hermit's Peak and Calf Canyon Fires merged on April 27, 2022, and both fires were reported as the Hermit's Peak Fire or the Hermit's Peak/Calf Canyon Fire. By May 2, 2022, the fire had grown, causing evacuations in multiple villages and communities in San Miguel County and Mora County, including the San Miguel County jail, the State's psychiatric hospital, the United World College, and New Mexico Highlands University.3 At the request of

New Mexico Governor Lujan Grisham, President Biden issued a major disaster declaration on May 4, 2022.⁴ The Hermit's Peak/Calf Canyon Fire was not 100 percent contained until August 21, 2022.⁵

The Act provides compensation to injured persons impacted by the Fire. It requires FEMA to design and administer a claims program to compensate victims of the Fire, for injuries resulting from the fire and to provide for the expeditious consideration and settlement for those claims and injuries. The Act further directs FEMA to establish an arbitration process for disputes regarding claims.

This interim final rule establishes the procedures for the processing and payment of claims to those injured by the Fire sustaining property, business, and/or financial losses. FEMA's procedures in this interim final rule are generally consistent with prior processes established for claims associated with the Cerro Grande Fire Assistance Act.⁶ Specific discussion and request for comment is provided where FEMA seeks to revise and/or modernize that process. As referenced above, FEMA plans to hold in-person public meetings during the 60-day comment period.

The first step in the claims process under this part is for the Claimant to file a Notice of Loss with the Office of Hermit's Peak/Calf Canyon Fire Claims ("Claims Office"). After receipt and acknowledgement by the Claims Office, a Claims Reviewer will contact the

¹ Section 102(a)(1) and (2), Hermit's Peak/Calf Canyon Fire Assistance Act, Public Law 117–180, 136 Stat. 2114 (2002). See also "Las Dispensas Prescribed Burn Declared Wildfire," Apr. 6, 2022 found at https://inciweb.nwcg.gov/incident/article/8049/68044/ (last accessed Sept. 15, 2022) and Theresa Davis, "How 'good fires' can turn into wildfires," Albuquerque Journal, Apr. 30, 2022 found at https://www.alqjournal.com/2494692/how-good-fires-can-turn-into-wildfires.html (last accessed Sept. 15, 2022).

² See Bill Gabbert, "Investigators determine Calf Canyon Fire caused by holdover from prescribed fire," Wildfire Today, May 27, 2022 found at https://wildfiretoday.com/ ?s=calf+canyon+holdover*apbct_email_id_ search_form_34270= (last accessed Oct. 6, 2022).

 $^{^3\,}See$ Bill Gabbert, ''Calf Canyon/Hermits Peak Fire grows to more than 120,000 acres,'' Wildfire

Today, May 2, 2022 found at https://wildfiretoday.com/2002/05/02/calf-canyon-hermits-peak-fire-grows-to-more-than-120000-acres/ (last accessed Sept. 15, 2022). See also Bryan Pietsch and Jason Samenow, "New Mexico blaze is now largest wildfire in state history," The Washington Post, May 17, 2022 found at https://www.washingtonpost.com/nation/2022/05/17/calf-canyon-hermits-peak-fire-new-mexico/ (last accessed Sept. 15, 2022).

⁴⁸⁷ FR 33808 (June 3, 2022).

⁵"Hermits Peak/Calf Canyon Fire 100 percent contained, fire officials say," The New Mexican, Aug. 21, 2022 found at https://www.santafenewmexican.com/news/local_news/hermits-peak-calf-canyon-fire-100-percent-contained-fire-officials-say/articles_5ac054fc-21a1-11ed-9401-134e852ee0a8.html (last accessed Sept. 15, 2022).

⁶The Cerro Grande Fire Assistance Act (Pub. L. 106–246 (2001)) required FEMA to design and administer a program for fully compensating those who suffered injuries resulting from the Cerro Grande Fire. The Cerro Grande fire resulted from a prescribed fire ignited on May 4, 2000, by National Park Service fire personnel at the Bandelier National Monument, New Mexico under an approved prescribed fire plan. That fire burned approximately 47,750 acres and destroyed over 200 residential structures. The Cerro Grande Fire Assistance Act process is detailed in an Interim Final Rule (65 FR 52259 (Aug. 27, 2000) and a Final Rule (66 FR 15847 (Mar. 21, 2001) that is now codified at 44 CFR part 295.

claimant to review the claim and help the claimant formulate a strategy for obtaining any necessary supporting documentation to complete the Proof of Loss. After discussion of the claim with the Claims Reviewer, the claimant will review and sign a Proof of Loss and submit it to the Claims Office. The Claims Reviewer will submit a report to the Authorized Official for review to determine whether compensation is due to the claimant. The Authorized Official's written decision will be provided to the claimant. If satisfied with the decision, the claimant will receive payment after returning a completed Release and Certification Form. If the claimant is not satisfied with the decision, an Administrative Appeal may be filed with the Director of the Claims Office. If the claimant is not satisfied after appeal, the dispute may be resolved through binding arbitration or heard in the United States District Court for the District of New Mexico. The specific proposals in this rule are more fully described below.

III. Discussion of the Interim Final Rule

This interim final rule adds 44 CFR part 296 to establish the procedures for processing and payment of claims to those injured by the Fire sustaining property, business, and/or financial losses.

A. Subpart A—General

Subpart A provides a general introduction and overview of the process.

1. Section 296.1 Purpose

This section provides for the purpose of the regulation, which is to establish the Office of Hermit's Peak/Calf Canyon Fire Claims to evaluate, process, and pay actual compensatory damages for injuries suffered from the Fire.

2. Section 296.2 Policy

This section explains FEMA's policy to provide expeditious resolution of damage claims for those injured by the Fire. The policy requires sensitivity to claimants' situations in administering the process.

3. Section 296.3 Information and assistance

This section provides information on the Claims Office and general information about assistance available as a result of the Fire.

4. Section 296.4 Definitions

This section provides definitions for the relevant regulatory terms, consistent with the Act and terms defined in the Cerro Grande Fire Assistance process

found at 44 CFR part 295. FEMA is adding definitions for "Administrator," "Claims Office," and "Hermit's Peak/ Calf Canyon Fire" consistent with the Act's definition of these terms. FEMA is including a definition of "Director" to mean the Independent Claims Manager appointed by the Administrator who will lead the Claims Office. FEMA is adding a definition of "Good Cause" to further explain when FEMA will allow claimants to extend the deadline for filing, supplementing claims, or reopening a claim for good cause. FEMA is incorporating a definition for "Injury" similar to the definition of "Loss" found in the Cerro Grande Fire Assistance process to reflect the terminology of the Act, and an updated definition of "Indian Tribe," "Notice of Loss," and "Proof of Loss" to reflect the definitions and updated requirements found in the Act. FEMA is also including a definition for "Individual Assistance" consistent with the definition found at 44 CFR 206.2. Finally, FEMA is including a definition for "Subrogee" to mean an insurer or other third party that has paid compensation to a claimant for injury and subrogated to any right the claimant has to receive payment under the Act.

5. Section 296.5 Overview of the Claims Process

The claims process is generally described in this section and is generally consistent with the process established in the Cerro Grande Fire Assistance process at 44 CFR part 295. The claimant must first file a Notice of Loss with the Claims Office, A Claims Reviewer will then contact the claimant to review the claim and help the claimant formulate a strategy for obtaining any necessary supporting documentation. After discussion of the claim with the Claims Reviewer, the claimant will review and sign a Proof of Loss. The Proof of Loss will document all injuries and loss of property, business losses, and financial losses pursuant to the Act. The Claims Reviewer will fully evaluate the claim and submit a report to the Authorized Official for review to determine whether compensation is due to the claimant. The Authorized Official's written decision will be provided to the claimant. If the claimant is satisfied with the decision, payment will be received upon return of a completed Release and Certification Form. If the claimant is not satisfied with the decision, an Administrative Appeal may be filed with the Director of the Claims Office. If the claimant is not satisfied after appeal, the dispute may be resolved through binding arbitration or

heard in the United States District Court for the District of New Mexico.

B. Subpart B—Bringing a Claim Under the Hermit's Peak/Calf Canyon Fire Assistance Act

Consistent with the Cerro Grande Fire Assistance claims process, subpart B explains the procedure for filing a claim under the Act.

1. Section 296.10 Filing a Claim Under the Hermit's Peak/Calf Canyon Fire Assistance Act

Any Injured Person can file a Notice of Loss to bring a claim under the Act which must include a brief description of each injury. FEMA will only accept a Notice of Loss form to bring a claim to ensure efficient and consistent processing of all claims associated with the Fire. FEMA reminds claimants in paragraph (a) that the Notice of Loss must contain a brief description of each injury, as defined in section 296.4. For the convenience of claimants, FEMA is offering the option for a single Notice of Loss submission for a household so long as all those injured are identified. Paragraph (c) explains the signature process for the Notice of Loss. If the claimant is an entity or individual who lacks the legal capacity to sign the Notice of Loss, then and only then can a duly authorized legal representative of the claimant sign the Notice of Loss. The same principle applies to affidavits submitted in support of claims, the Proof of Loss, and the Release and Certification Form. Public adjusters and attorneys may not sign documents filed under the Act on behalf of individual claimants who have the legal capacity to execute these documents.

Paragraph (e) modernizes the process by providing options to file the Notice of Loss by mail, electronically, or in person. Details regarding the filing process can be found at http://www.fema.gov/hermits-peak. FEMA seeks comment on whether this update will improve the overall claims process. Paragraph (f) clarifies that the Notice of Loss is deemed to be filed on the date received and acknowledged by the Claims Office if completed and properly signed.

2. Section 296.11 Deadline for Notifying FEMA of Injuries

Pursuant to the Act, the deadline to file a Notice of Loss is two years after the date the interim final rule is promulgated or November 14, 2022. There is no ability to extend this deadline under the Act and section 296.11 provides clear instructions regarding the deadline to ensure claimants are informed of the timeline

by which to submit their Notice of Loss. FEMA cannot provide compensatory damages for an injury unless the claimant has reported it to FEMA by November 14, 2024. Sections 296.34 and 296.35 below establish a process for notifying FEMA of injuries that are not referenced in the initial Notice of Loss. Whether a claimant tells FEMA about an injury in the initial Notice of Loss or an amendment under section 296.34, FEMA must know about the injury by November 14, 2024.

3. Section 296.12 Election of Remedies

The Act permits an Injured Person to seek compensation through one of three mechanisms: (1) the Act; or (2) the Federal Tort Claims Act; or (3) a civil lawsuit against the United States (if authorized by another law). The Act further provides that a claimant's choice of one of these three mechanisms becomes "final and conclusive on the Claimant . . . upon acceptance of an award." Therefore, in paragraph (a), FEMA clarifies that Injured Persons who accept an award under the Act waive the right to pursue any claims arising out of or relating to the same subject matter, whether through the Federal Tort Claims Act or a civil lawsuit. Under paragraph (b), any person or entity who accepts an award on a claim under the Federal Tort Claims Act or a civil action against the United States, or any employee, officer, or agency of the United States for fire-related claims waives the right to pursue any claims for injuries arising out of or relating to the same subject matter. FEMA seeks comment on the best means of implementing the Act's election of remedies provision.

4. Section 296.13 Subrogation

Section 296.13 describes the procedures to be used by insurers (or other third parties with the rights of a Subrogee) for submitting subrogation claims. This section is generally consistent with the Cerro Grande Fire Assistance process. The procedures described in paragraphs (c) through (f) of section 295.10 apply with equal vigor to subrogation claims, including the requirement that the Notice of Loss be received by November 14, 2024. No subrogation claim will be considered unless the Subrogee elects the Act as its exclusive mechanism for seeking compensation from the United States for all Hermit's Peak/Calf Canvon Firerelated subrogation claims and any other Hermit's Peak/Calf Canyon Firerelated injuries. FEMA will reject a subrogation claim to recover payments until the Subrogee has paid the insured everything that the Subrogee believes

that the Injured Person is entitled to receive under the policy. A Notice of Loss may be filed if there is a dispute between the Injured Person and the Subrogee, which is pending before a third party (e.g., appraiser, arbitrator, or court), provided that the insurer has made the final payment that it believes that the insured is entitled to receive under the policy.

5. Section 296.14 Assignments

Consistent with the Cerro Grande Fire Assistance process, this section prohibits assignment of claims. It also prohibits assignment of the right to receive payment for claims. FEMA intends to make the Act's compensation payments only to the injured claimant.

C. Subpart C—Compensation Available Under the Hermit's Peak/Calf Canyon Fire Assistance Act

Subpart C describes the compensation available under the Act. Section 104(c)(3) of the Act limits payments under the Act to "actual compensatory damages measured by injuries suffered" and shall not include "interest before settlement or payment of a claim; or punitive damages." Consistent with the Cerro Grande Fire Assistance process, FEMA views the terms "compensation," "damages," and "compensatory damages" under the Act as synonyms and uses them interchangeably in this interim final rule. FEMA may only compensate claimants for damages that resulted from the Fire. Each claim will be reviewed on its unique facts and merits. Claimants should not assume that an injury resulting from the Fire is not compensable simply because the regulation fails to address it specifically. Claimants should include all injuries resulting from the Fire on the Notice of Loss. Generally speaking, FEMA will determine compensatory damages in accordance with the laws of the State of New Mexico, except where the Act is more generous. If FEMA denies a claim, an explanation of the reasons for doing so will be provided.

1. Section 296.20 Prerequisite to Compensation

Consistent with the Cerro Grande Fire Assistance process, a claimant must be an Injured Person who suffered an injury as a result of the Fire and sustained damages to receive compensation under the Act.

2. Section 296.21 Allowable Damages

As required by the Act, FEMA will provide for payment of actual compensatory damages under paragraph (a). Consistent with the Act ⁷ and Cerro Grande Fire Assistance process, FEMA will apply the laws of the State of New Mexico to the calculation of damages. Damages must be reasonable in amount. To reduce complexity in the process, FEMA has eliminated language referencing reasonable steps to reduce damages.

Consistent with the Act and the Cerro Grande Fire Assistance process, paragraph (b) provides that FEMA will not reimburse claimants for attorneys' fees or agents' fees. Our treatment of attorney and agent fees is consistent with the Act. Section 104(j) of the Act limits the fees that an attorney or agent may charge a client. It does not provide that FEMA will reimburse claimants for attorneys' or agents' fees and this exclusion applies to attorney and agent fees incurred in the prosecution of a claim under the Act. FEMA also notes that the Act does not regard attorneys' fees as compensatory damages. Attorneys' fees are not considered compensatory damages in tort actions under New Mexico law.8 Further, the statutory damages under New Mexico law ⁹ may not be recovered as Congress did not authorize FEMA to pay statutory damages in the Act.

Paragraphs (c) through (e) explain how FEMA plans to approach the types of claims the agency expects to encounter most frequently. FEMA addressed all three categories of damages allowed under the Act—property, business, and/or financial losses—but made a deliberate choice not to address all the examples of such categories enumerated under the Act. There is no intention to limit the right of claimants in this section. Claimants may recover all damages allowable under section 104(d)(4) of the Act.

Consistent with the approach taken in the Act, paragraph (c) sets out FEMA's approach to compensating for property losses. Paragraph (c)(1) explains FEMA's approach to loss of real property and contents. FEMA will provide compensatory damages for the damage or destruction of a property and its contents, including the reasonable cost of reconstruction of a structure comparable in design, construction materials, size, and improvements. FEMA will calculate these costs using post-fire construction costs in the locality that a damaged or destroyed structure existed before the Fire. FEMA will compensate property owners to

⁷ Section 104(c)(2), Hermit's Peak/Calf Canyon Fire Assistance Act, Public Law 117–180, 136 Stat. 2114, 2168 (2022).

⁸ See New Mexico Right to Choose/NARAL v. Johnson, 127 N.M. 654 (1999).

⁹ See NM Stat. Ann. § 30-21-4.

rebuild their structures in accordance with the building codes and standards applicable at the time that their claim is processed, regardless of whether the destroyed structure complied with codes and standards before the Fire. To process claims within a timely manner, FEMA may be required to estimate a property owner's costs well before construction is completed. Property owners who decide to rebuild and later find that their actual costs exceeded FEMA's estimate may supplement or reopen their claims under Sections 296.34 and 296.35 of this interim final rule.

In paragraph (c)(2), FEMA is limiting compensation for trees and other landscaping to 25 percent of the pre-fire value of the structure and lot. This approach is generally consistent with the approach taken in the Cerro Grande Fire Assistance process. Under New Mexico tort law, damages are awarded for destroyed or damaged trees based on the value of the trees destroyed or the difference in value of the real estate with and without the trees. 10 This 25 percent limitation does not apply to business losses for timber, crops, and other natural resources under section 296.21(d). The New Mexico tort law formula is a less generous formula than the replacement cost calculation FEMA implemented in the Cerro Grande Fire Assistance process. FEMA is implementing the same formula as the Cerro Grande Fire Assistance process now.

Paragraph (c)(3) is intended to implement section 104(d)(4)(A)(ii) of the Act, which authorizes FEMA to pay "otherwise uncompensated damages resulting from the Hermit's Peak/Calf Canyon Fire for . . . a decrease in the value of real property." Consistent with the Cerro Grande Fire Assistance process, paragraph (c)(3) allows FEMA to compensate for realized losses in the value of real property, i.e., land and structure, to the extent that such losses have not been fully compensated either through compensation under paragraph (c)(1) or otherwise. To be awarded compensatory damages, paragraph (c)(3) requires the claimant to either sell the real property in a good faith arm's length transaction that closes no later than November 14, 2024 and the claimant realizes a loss in the pre-fire value (see paragraph (c)(1)); or the claimant can establish that the real property value was permanently diminished as a result of the Fire (see paragraph (c)(2)). Losses involving the

value of commercial real estate will be evaluated on a case-by-case basis.

Paragraph (c)(4) addresses compensation to Injured Persons for Subsistence Resources losses. FEMA is generally mirroring the Cerro Grande Fire Assistance process for subsistence in this section, but consistent with section 104(d)(4)(A)(iv) of the Act, FEMA is not limiting compensation to Indian Tribes, Tribal entities, Tribal Members, or Households including Tribal Members but rather allowing this compensation for all Injured Persons that have sustained Subsistence Resource losses. Reimbursement is available for the reasonable cost of replacing Subsistence Resources used by a claimant prior to the start of the Fire, but that are no longer available to the claimant as a result of the Fire. Claimants may receive either compensatory damages for the increased cost of obtaining subsistence resources from lands not damaged by the Fire or for the cost of procuring substitute Subsistence Resources in the cash economy. Compensatory damages will be paid for the period between April 6, 2022, and the date when subsistence resources can reasonably be expected to return to the level of availability that existed before the Fire. Long-term damages for subsistence resources will be made in the form of lump sum cash payments to eligible claimants.

In paragraph (d), FEMA addresses business losses. Consistent with the Act, FEMA will award compensatory damages for damage to tangible assets or inventory, including timber, crops, and other natural resources; business interruption losses; overhead costs; employee wages for work not performed; loss of business net income; and any other loss that the Administrator determines to be appropriate for inclusion as a business loss.

Paragraph (e) discusses financial losses. Consistent with the Act, these losses include increased mortgage interest costs, insurance deductibles, temporary or relocation expenses, lost wages or personal income, emergency staffing expenses, debris removal and other cleanup costs, costs of reasonable heightened risk reduction, premiums for flood insurance, and any other loss that the Administrator determines to be appropriate for inclusion as a financial loss. Paragraph (e)(1) addresses recovery loans and provides for reimbursement of loans, including Small Business Administration (SBA) disaster loans obtained after April 6, 2022, for damages resulting from the Fire. Consistent with the Cerro Grande Fire Assistance process, FEMA will

reimburse interest for the period beginning on the date the loan was taken out and ending on the date when the claimant receives a compensation award (other than partial payment). Claimants are required to use the proceeds of their compensation awards to repay the SBA disaster loans and FEMA will coordinate with the SBA to formulate procedures for assuring repayment contemporaneously with the compensation award receipt.

Paragraph (e)(2) addresses the requirement from the Act that claimants be eligible for compensation for flood insurance premiums. Consistent with the Act, claimants that were not required by law to maintain flood insurance before the Fire and did not have such insurance before the Fire may receive reimbursement for the cost of reasonable flood insurance premiums for a two-year period for their owned or leased real property if required to purchase flood insurance. Because there has not been sufficient time to revise flood zone maps since the Fire, some claimants who may have legitimate reasons for concern may not be required to maintain flood insurance. FEMA is exercising the discretion in section 104(d)(4)(C)(x) to allow compensation for flood insurance premiums if the claimant purchased flood insurance after the Fire due to the fear of heightened flood risk. FEMA may also provide flood insurance directly through a group or blanket policy.

Consistent with the Cerro Grande Fire Assistance process, paragraph (e)(3) states that FEMA may reimburse claimants for reasonable out of pocket treatment costs for mental health conditions resulting from the Fire. FEMA is offering reimbursement for treatment received between April 6, 2022 and April 6, 2024. Damages for mental health conditions are not recoverable under New Mexico law, except in a very limited class of cases. While FEMA will reimburse claimants for these expenses, given the limitation of New Mexico law FEMA will not entertain subrogation claims for mental health treatment unless those expenses could be recovered in a tort action under New Mexico law.

During the fire and its immediate aftermath, many individuals, charitable organizations, businesses, and other entities made voluntary donations of cash, goods, and services to assist the fire fighting and fire recovery effort and to help those affected by the Fire. Consistent with the Cerro Grande Fire Assistance process, in paragraph (e)(4) FEMA will compensate claimants for the cost of merchandise, use of equipment, or other non-personal

 $^{^{10}\,}See$ Mogollon Gold & Copper Co. v. Stout, 14 NW 245 (1907).

services, directly or indirectly donated to survivors of the Fire, if donated no later than September 20, 2022. Given the scope of the Fire, FEMA believes a 30-day period after containment of the Fire constitutes an appropriate time frame for these donations to be reimbursable; however, the agency seeks comment on whether this time period is sufficient. Donations will be valued at cost. FEMA is removing compensation for discounts as provided in the Cerro Grande Fire Assistance process, as the agency currently lacks information about whether such discounts were provided in the wake of the Fire. However, FEMA seeks comment on whether claimants should be able to seek compensation for discounts on goods and services offered to fire survivors as well as on the method for calculating such compensation should FEMA amend its regulations to authorize compensation for discounts on goods or services offered to fire survivors.

Section 104(d)(4)(C)(vii) of the Act grants FEMA the authority to compensate claimants for reasonable efforts to reduce an increased risk to their property from wildfires, floods, or other natural disasters. Consistent with the Act and with the Cerro Grande Fire Assistance process, paragraph (e)(5) provides that FEMA will reimburse claimants for reasonable efforts to reduce risk back to levels prevailing before the Fire. Such measures may include, for example, risk reduction projects that reduce an increased risk from flooding, mudslides, and landslides in and around burn scars in an amount not to exceed 25 percent of the higher of compensation from all sources, (i.e., the Act, insurance, and FEMA assistance under the Stafford Act), for damage to the structure and lot, or the pre-fire value of the structure and lot. Claimants seeking compensation under paragraph (e)(5) must include the claim in a Notice of Loss filed not later than November 14, 2024 or an amended Notice of Loss filed not later than November 14, 2025. This is the deadline provided by section 104(d)(4)(C)(vii) of the Act. Claimants should take into account current building codes and standards and consider nature-based solutions 11 to reduce their heightened risk. Claimants must complete the risk reduction project for which they receive compensation. FEMA believes paragraph (e)(5) clarifies the process for obtaining compensation for heightened risk reduction losses, regardless of the

type of structure the claimant owns. FEMA is increasing the total compensation available for risk reduction projects given the general increase in costs of such projects since the Cerro Grande Fire Assistance process was implemented and to encourage claimants to consider implementing nature-based solutions to reduce the heightened risks to their property as a result of the Fire. 12 FEMA seeks comment on whether the compensation is sufficient to reduce the heightened risk and whether naturebased solutions should be considered in risk reduction projects.

Paragraph (f) addresses insurance and other benefits. The Act allows FEMA to provide compensation only if damages have not been paid or will not be paid by insurance, a third party, or through another FEMA program. Claimants are not required to submit their claims to their insurance company nor are they required to pursue a settlement from their insurance company after filing a claim under the Act. FEMA encourages claimants to continue to pursue their insurance claims because this may expedite the process of reconstructing documentation that will be helpful to the claims process under the Act. If a claimant has received or expects to receive a payment from an insurance company, the actual or anticipated payment must be disclosed. If a claimant has not settled with the insurance company by the time FEMA is prepared to make a partial payment on the claim, FEMA will examine the insurance policy and determine what the agency reasonably expects the insurance company to pay. FEMA will review the issues again in the Authorized Official's determination. If the insurance company has not paid all that FEMA anticipated, FEMA can award the difference at the time that the Authorized Official's determination is made. FEMA notes that the State of New Mexico generally requires insurance companies to settle catastrophic claims brought by policyholders within 90 days of the date that the claim was reported to the insurer.13 FEMA expects that

most, if not all, insurance claims will be paid before the Authorized Official's determination is issued. However, in the event that the insurance claim is resolved after the Authorized Official's determination is issued and as a result the claimant is due additional compensation under the Act, the claimant should ask the Claims Office to reconsider the matter under sections 296.34 or 296.35.

Those Injured Persons eligible for disaster assistance under the Public Assistance Program are expected to apply for all available assistance, and compensation will not be awarded for specific costs or losses that are eligible under that program. Consistent with the Act, FEMA clarifies that the Federal share of costs for Public Assistance projects is 100 percent. Similarly, compensation under the Act will not be awarded for losses or costs that have been reimbursed under the Federal Assistance to Individual and Households Program. Those individuals that obtain assistance under the Individuals and Households Program are not precluded from filing a claim under the Act. Claimants may seek compensation for losses or costs that exceed the amount provided under the Individuals and Households Program. FEMA encourages all Injured Persons to seek assistance under the FEMA programs for which they are eligible. Those individuals suffering injuries that are compensable under State or Federal worker's compensation laws must apply for all benefits under such laws. Note that gifts or donations made to claimants by non-governmental organizations and individuals, other than wages paid by the claimant's employer or insurance payments, will be disregarded in evaluating claims and need not be disclosed by claimants.

D. Subpart D—Claims Evaluation

Subpart D explains the process after the claim is filed, including how claims are documented and how claimants can obtain payment if they agree with FEMA's evaluation.

1. Section 296.30 Establishing Injuries and Damages

Section 296.30 explains FEMA's approach to documentation of injuries which is generally consistent with the Cerro Grande Fire Assistance process. This section explains who has the burden of proof, the forms needed when going through the claims process and who has the authority to settle claims. FEMA expects that claimants will provide whatever documentation is reasonably available to support their claim.

¹¹ See https://www.fema.gov/emergencymanagers/risk-management/nature-based-solutions (last accessed Oct. 31, 2022).

¹² FEMA seeks to encourage Claimants to consider nature-based solutions consistent with Executive Order 14072 "Strengthening the Nation's Forests, Communities, and Local Economies," 87 FR 24851, Apr. 22, 2022.

¹³ See New Mexico Statutes Annotated Chapter 59A-16-20 (2021) found at https:// nmonesource.com/nmos/nmsa/en/item/4438/ index.do#!fragment/zoupio-_Toc110333083/ BQCwhgziBcwMYg K4DsDWszIQewE4BUBTADwBdoAvbRABw EtsBaAfX2zgEYOAGAZn+4AOXgEoANMmyl CEAIqJCuAJ7QA5KrERCYXAnmKVqraVIAbQg AIAggDkAÍheR1khUko1adCAMp5 SAIRUAJQBRABkQgDVbAGEQsVIwACNo T10QEREgA (last accessed Sept. 27, 2022).

Once a claimant has begun the process set out in section 296.30, the claims office assigns a Claims Reviewer to the claim. The Claims Reviewer will review, investigate, and objectively evaluate the claim for the Claims Office. Claims Reviewers cannot function as agents or representatives of the claimant. Claims Reviewers will be proactive in helping claimants identify injuries and in formulating a strategy for proving them and in assisting claimants in locating documentation that may be available from third-party sources. Claimants may be asked to sign release forms authorizing FEMA's Claims Reviewers to obtain information and documentation from third-party sources.

Section 295.30(a) states that the claimant bears the burden of proof for establishing all elements of the injury and compensatory damages. This paragraph also provides claimants the opportunity to make a record supporting the claim by submitting any information or documentation that they deem relevant. The responsibility for making this record rests with the claimant, not the Claims Reviewer. As FEMA must support compensation decisions with evidence, the agency expects claimants will provide whatever evidence is reasonably available to corroborate the nature, extent, and value of their losses. If documentation or substantiating evidence of an injury or damage is not reasonably available (e.g., it burned in the fire), the Claims Office may determine that the claimant's statement alone will be sufficient to substantiate the injury or damage based on the unique circumstances presented by each case, taking into consideration potential alternative sources of substantiation and documentation. Paragraph (a) authorizes the Claims Office to ask claimants to provide affidavits to support the claim. FEMA is, however, sensitive to privacy concerns of claimants. Where FEMA believes an affidavit from a close associate of the claimant will strengthen the claim, the agency may suggest that the claimant obtain one. FEMA will not automatically reject the claim if the claimant declines to provide the affidavit. FEMA will consider all evidence in the record, including an alternative substantiation offered by the claimant, in making a decision. Paragraph (a) also reminds claimants that FEMA may require an inspection of real property as part of the claims process and their establishment of injuries and damages. FEMA is advising claimants who have suffered business losses that they may expedite resolution of their claim if they voluntarily provide copies of their income tax returns.

Claimants who decline to submit their income tax return voluntarily during the claims review process must sign an affidavit agreeing to produce the returns if requested by the Department of Homeland Security's Office of the Inspector General (DHS OIG) or the General Accounting Office (GAO) in the course of an audit.

Under paragraph (b), claimants are required to attest to the nature and extent of each injury of which compensation is sought in the Proof of Loss. Before the Authorized Official's determination can be issued, the claimant must sign the Proof of Loss. This Proof of Loss must be signed under penalty of perjury by the claimant or the claimant's legal representative in specific circumstances. Paragraph (b) also sets forth the deadline by which a Proof of Loss must be submitted after a Notice of Loss and allows discretion for good cause to extend that deadline. For example, a claimant, through no fault of their own, may not be able to access needed documentation in time to submit a claim and the Director of the Claims Office may consider those circumstances as good cause to extend the deadline. It is in both the claimant's interest and FEMA's interest that claims be expeditiously resolved. The intent of the Act is to compensate fire survivors as quickly as possible. Congress entrusted FEMA with administering an orderly compensation process. Section 104(d)(1)(A)(i) of the Act states that FEMA must determine the compensation due to a claimant within 180 days of the date upon which the Notice of Loss is filed. It is impossible for FEMA to fulfill this mandate if claimants are unwilling to provide specific details about their injuries by signing the Proof of Loss. While FEMA believes that Congress intended for the agency to have the flexibility to provide claimants with extra time document their injuries in appropriate cases, nothing in the Act suggests that claimants should be able to keep their claims open for an extended period of time. Claimants who submit their Notice of Loss should submit a signed Proof of Loss to the Claims Office not later than 150 days after the initial Notice of Loss was submitted. Adherence to this deadline will leave FEMA with 30 days to determine the compensation due to the claimant and enable the agency to meet the 180-day timeframe required by Congress. To provide a claims process that is orderly for all and to meet the agency's obligation to be good stewards of the Federal funds provided by Congress for administration of the program, Claimants must comply with

the timeframes for signing a Proof of Loss set forth in this paragraph. Section 104(d)(1)(A)(i) of the Act assumes that the claimant will fully cooperate with FEMA in the adjudication of the claim to ensure a timely determination. FEMA will try to process claims in less than 180 days but may require the full 180-day period in many cases. Partial payments are intended to ease the burden on the claimant during this period.

There is flexibility built into the process for claimants to tell FEMA about injuries and damages that they could not have discovered or did not remember when they signed the Proof of Loss. Sections 296.34 and 296.35 explain this flexibility. If a claimant is not prepared to sign a Proof of Loss, for good cause, an extension may be requested from the Director of the Claims Office. Extensions will not be granted automatically, but only on consideration of the equities in the request. Alternatively, the claimant may withdraw the claim and re-file the claim once before November 14, 2024, when the injuries are better defined. If a claimant does not complete the Proof of Loss within the timeframes specified in this paragraph or fails to obtain an extension, the Claims Office may administratively close the claim.

Paragraph (c) requires claimants who receive compensation to sign and return a Release and Certification Form, including for partial payments under section 296.33. The Release and Certification Form must be received before the Claims Office provides payment on the claim. FEMA is simplifying the process from the Cerro Grande Fire Assistance process to eliminate specific timelines and would rather tie the return of the form to payment. Section 104(e) of the Act provides that at the end of the process, the United States and all employees, officers, and agencies of the United States are released from all claims related to the Fire and the compensation settlement is conclusive for the claimant. The Act does not bar the United States from recovering payments made to the claimant after the return of the Release and Certification Form. The Act was intended to provide a more expeditious and less adversarial process for compensation than is available under the Federal Tort Claims Act. Paragraph (c) provides that the United States will not attempt to recover monies paid to claimants completing this process, except in the case of fraud or misrepresentation by the claimant or the claimant's representative, failure of the claimant to cooperate with an audit as required by section 296.36, or a

material mistake by FEMA. The Act generally obligates FEMA to attempt to recover payments where there is evidence of civil or criminal fraud, misrepresentation, presentation of a false claim or where a claimant was not eligible for a partial payment received pursuant to the Act. 14 FEMA may also recover overpayments where the agency made a material mistake in calculation of the damages owed to the claimant and in other appropriate cases.

Paragraph (d) authorizes the Director of the Claims Office to offer claimants an opportunity to settle or compromise a claim in whole or in part at any time during the process. This authority allows flexibility in the process to help claimants recover more efficiently and is consistent with the Cerro Grande Fire Assistance process.

2. Section 296.31 Reimbursement of Claim Expenses

Early in the process, claimants should also discuss with the Claims Reviewer whether FEMA will require an appraisal or other third-party opinion of value to evaluate a claim. FEMA may order appraisals and third-party opinions directly or request the claimant to obtain them. Section 296.31 provides that if FEMA requests the claimant provide an appraisal or other third-party opinion, FEMA will reimburse the claimant for the reasonable cost of obtaining it. Paragraph (a) addresses the circumstances in which FEMA will reimburse a claimant for reasonable costs of third-party opinions obtained by the claimant. It provides that FEMA will do so only if the agency requests that the claimant procure the opinion. It is the claimant's responsibility to develop and submit whatever evidence they think is appropriate to support the claim. Claims preparation expenses are not regarded as compensatory damages under New Mexico law or under the Federal Tort Claims Act. Similarly, they are not recoverable under the Act. If FEMA requests that a claimant obtain a third-party opinion and the expert selected by the claimant believes they must consult with other experts to render the opinion, the claimant should notify the Claims Reviewer and provide an estimate of the total cost, FEMA will not reimburse the claimant for the cost of these other experts unless the Claims Office has expressly approved their use.

Compensatory damages for time spent in claims preparation are not available under New Mexico law or the Federal Tort Claims Act. Moreover, there is no evidence Congress intended that

claimants be compensated for the value of their time in preparing a claim. Providing compensation for a claimant's time would be difficult to administer, as FEMA would have to determine equitably the value of a claimant's time and to verify that claimants have expended the number of hours that are claimed. FEMA's payments under the Act are subject to independent audit by the GAO and the DHS OIG and claimants would likely find attempts by auditors to verify the payment for hours spent in the claims process highly intrusive. However, as with the Cerro Grande Fire Assistance process, FEMA is choosing to exercise discretion to provide a lump sum payment to claimants for miscellaneous and incidental expenses incurred in the claims process. Subrogation claimants and claimants whose only Fire-related loss is the cost of a flood insurance premium are not eligible for the lump sum payment. FEMA will provide a lump sum payment of five percent of the insured and uninsured loss (excluding flood insurance premiums), not to exceed \$25,000. The minimum lump sum payment is \$150.15 The payment amounts for these miscellaneous and incidental expenses are based upon the Cerro Grande Fire Assistance process and have been updated to reflect inflationary increases since that rule was published. 16 FEMA believes that paragraph (b) represents a fair and reasonable accommodation between the agency's responsibility to spend Federal funds wisely and the desire to compensate claimants as fully as possible. The lump sum payment under paragraph (b) will be made after a properly executed Release and Certification Form is returned to the Claims Office and cannot be obtained through partial payment.

3. Section 296.32 Determination of Compensation Due to Claimant

Section 296.32 explains how FEMA will evaluate claims. Claims Reviewers do not have the authority to determine whether a claim is eligible for compensation or how much compensation will be paid. Their role is to work with the claimant to obtain relevant evidence, analyze the evidence, and make a recommendation to an Authorized Official. Each claim will be

assigned to an Authorized Official, and only Authorized Officials have the authority to decide claims.

When the Authorized Official has decided a claim, they will send a written notification to the claimant's address as it appears in the Claims Office records. The date that appears on this notification starts a 120-day clock during which a claimant must either accept the finding or appeal it. The procedure for appealing an Authorized Official's determination is explained in section 295.41. If the claimant has not acted at the end of this period, they may forfeit further rights to an Administrative Appeal. The Director of the Claims Office may modify the 120day deadline if good cause exists.

4. Section 296.33 Partial Payments

This section explains the partial payment process. Section 104(d)(2) of the Act authorizes FEMA to make partial payments at the request of the claimant. As in the Cerro Grande Fire Assistance process, the Claims Office may make one or more partial payments to the claimant if there is a reasonable basis to estimate the claimant's damages. FEMA believes this section offers sufficient discretion to the agency to make partial payments of any amount and to expedite payments where it is appropriate to do so. The amount of a partial payment in any particular case will depend on the nature of the claim and in some cases, how well the claim is supported. FEMA encourages claimants who require expedited payments to discuss the matter with a Claims Reviewer. FEMA is updating the Cerro Grande Fire Assistance process by requiring claimants to sign a Release and Certification Form as part of the partial payment process. This change simplifies the requirement that the Form be submitted to receive any payment. While the Claims Office's decision to provide a partial payment cannot be appealed, acceptance of a partial payment does not affect the claimant's ability to pursue an appeal, arbitration, or other options under the Act with respect to any portion of a claim for which a Release and Certification Form is not executed.

5. Section 296.34 Supplementing Claims

Section 104(d)(1)(A)(i) of the Act requires FEMA to determine and fix the amount to be paid for a claim within 180 days after the claim is submitted. To meet this deadline, FEMA may ask claimants to sign the Proof of Loss and require that the Authorized Officials render a definitive determination more expeditiously than some claimants

¹⁴ See Section 104(l), Public Law 117-180, 136 Stat. 2114, 2168.

¹⁵ The Cerro Grande Fire Assistance regulations at 44 CFR 295.31(b) provided for a lump sum payment of \$100 or 5% of the compensatory damages, not to exceed \$15,000.

 $^{^{16}}$ Inflationary adjustments have been made based on the Consumer Price Index for All Urban Consumers as published by the U.S. Department of Labor. See generally https://www.bls.gov/data/ inflation_calculator.htm.

would prefer. Section 296.34 provides claimants with the flexibility to make additional claims after submitting a Proof of Loss and before submission of the Release and Certification Form. Before signing the Proof of Loss, the claimant may amend the Notice of Loss to seek compensation for injuries not referenced in the Notice of Loss. claimants who wish to amend the Notice of Loss should contact the Claims Reviewer. The additional injuries will be noted on the Proof of Loss and will be adjudicated in the Authorized Official's determination. Once the claimant has signed the Proof of Loss, they may request permission from the Director of the Claims Office to amend the Notice of Loss for consideration of one or more injuries not addressed in the Proof of Loss. The claimant should consult with the Claims Reviewer about the procedure for obtaining permission of the Director of the Claims Office. The Director of the Claims Office will grant the request if it is supported by good cause. If the request is granted, the Director will determine whether compensation is due for the additional injury under the Administrative Appeal procedures described in subpart E of part 296. The additional injury will not be considered until after the Authorized Official's determination is issued on the remainder of the claim. If the claimant decides to appeal the Authorized Official's determination on other injuries, the Director of the Claims Office will decide both matters in a single appeal proceeding. Claimants are reminded that they must put the Claims Office on notice of any injury not mentioned in the initial Notice of Loss not later than the deadline for filing an Administrative Appeal under section 296.41 or November 14, 2024, whichever is earlier. A written request for permission to amend a Notice of Loss after the Proof of Loss is signed must be on file with the Director of the Claims Office no later than the deadline for filing an Administrative Appeal under section 296.41 or November 14, 2024, whichever is earlier.

6. Section 296.35 Reopening a Claim

Section 296.35 provides for reopening a claim after the claimant has submitted a Release and Certification Form again with the goal to allow claimants an opportunity to request damages in excess of those previously awarded. In appropriate cases, the claimant can use the reopening provision of this section to seek compensation for an injury not previously reported to FEMA. Specifically, claimants may request to reopen if, not later than November 14,

2025, the claimant desires heightened risk reduction compensation under section 296.21(e)(5): the claimant closed the sale of a home and wishes to present a claim for a decrease in the value of the real property under section 296.21(c)(3); or the claimant has incurred additional losses under section 296.21(c)(1) as part of a reconstruction in excess of those previously awarded. Requests to reopen for good cause will only be granted in the Director's discretion. The Director's decision to reopen or not reopen a claim is not subject to review under the arbitration provisions of Subpart E of this part. Reopened claims will not be decided by the Director of the Claims Office but by an Authorized Official, after considering the recommendation of the Claims Reviewer. Claimants who are dissatisfied with the Authorized Official's determination on the reopened claim may appeal to the Director of the Claims Office pursuant to subpart E of part 296.

7. Section 296.36 Access to Records

Claimants are required to grant the DHS OIG and the Comptroller General of the United States access to the subject property and to records and information in their control that are relevant to their claims for purposes of audit and investigation. These records include, but are not limited to, any relevant tax records. The Act requires that the GAO, a legislative branch agency, audit claims and payments made under the Act. The DHS OIG is responsible for investigating charges of fraud and abuse and auditing FEMA's programs.

8. Section 296.37 Confidentiality of Information

The Privacy Act protects the confidentiality of information provided by individual claimants. This information may only be disclosed with the consent of the claimant or pursuant to a routine use, which has been disclosed to the public. Confidential, proprietary, and trade secret information provided by entities, such as business, Indian Tribes, Tribal entities, and government agencies, are not eligible for Privacy Act protection, but may be exempt from disclosure under the Freedom of Information Act. Non-individual claimants are encouraged to discuss the need to protect confidential information from disclosure with FEMA before the information is submitted. FEMA may not be able to prevent the disclosure of this information without awareness of its confidential nature.

E. Subpart E—Dispute Resolution

Subpart E discusses a claimant's rights if they disagree with FEMA's evaluation of the claim.

1. Section 296.40 Scope

Claimants are afforded a right to appeal the initial determination to the Director of the Claims Office. This is referred to as an Administrative Appeal. If the claimant is dissatisfied with the Administrative Appeal decision, they may put the matter to binding arbitration or seek judicial review in federal court.

2. Section 296.41 Administrative Appeal

Section 296.41 describes the Administrative Appeal process. Consistent with the Cerro Grande Fire Assistance process, claimants disagreeing with the conclusions of FEMA's Authorized Official under section 296.32 must pursue an Administrative Appeal before initiating arbitration or seeking judicial review in federal court. An Administrative Appeal decision constitutes the final decision of the Director of the Claims Office. Pursuant to paragraph (a), a written request for an Administrative Appeal must be postmarked or electronically stamped within 120 days after the date of the Authorized Official's determination

FEMA requests that claimants provide the Claims Reviewer with all relevant evidence supporting the claim. The goal of the process is to render equitable compensation decisions the first time, not to encourage Administrative Appeals or further proceedings. However, paragraphs (c) and (d) allow for the claimant to submit supplemental filings and to present any relevant factual evidence concerning the issues under appeal, even if it was not presented earlier in the process to ensure claimants are fully heard. Claimants who wish to raise new claims or damage theories after submitting a Proof of Loss should ask the Director of the Claims Office to supplement their claim under section 296.34 of this part.

Under section 296.41, the Director of the Claims Office may request additional information, may schedule a conference, or may convene a hearing under paragraphs (e), (f), and (g) respectively. To ensure effective, efficient resolution of claims, FEMA is updating the process to allow claimants to request a mediator to facilitate a conference during the Administrative Appeal. This allows claimants to request a facilitator earlier in the process as part of the Administrative

Appeal at a conference in paragraph (f) instead of at the later arbitration stage of the process. FEMA believes this change will resolve claims faster consistent with the Act's purpose to expeditiously consider and settle claims. FEMA seeks comment on this update. Following the Administrative Appeal decision, if the claimant does not initiate arbitration or seek judicial review in the prescribed timelines, their concurrence with the decision will be conclusively presumed under paragraph (i). If the claimant concurs with the Director's decision, any additional damages will be paid upon receipt of a properly executed Release and Certification Form.

3. Sections 296.42 Arbitration

Section 104(h)(3)(A) of the Act requires FEMA establish procedures under which a dispute regarding a claim may be settled by arbitration. Section 296.42 establishes these procedures. Consistent with the Cerro Grande Fire Assistance arbitration process, any issue decided in an Administrative Appeal may be referred to binding arbitration. Paragraph (a) requires the written request for arbitration be electronically stamped or postmarked no later than 60 days after the Administrative Appeal decision date. FEMA is updating the process to allow for electronic submission of arbitration requests and seeks comment on this update. Evidence not previously entered into the Administrative Record will not be considered during arbitration under paragraph (b). A claimant cannot arbitrate an issue unless it was raised and decided in the Administrative

As explained above, FEMA is updating the process to allow claimants to request a mediator to facilitate a conference during the Administrative Appeal in 296.41(f). FEMA believes this change will resolve claims faster consistent with the Act's purpose to expeditiously consider and settle claims. FEMA seeks comment on this update.

Based on FEMA's experience with the arbitration process for the Cerro Grande Fire Assistance, the agency is updating paragraph (c) regarding arbitrator selection. Specifically, FEMA is changing the arbitrator selection process to a random drawing from a list of qualified arbitrators who have agreed to serve, rather than allowing the claimant to select an arbitrator from such a list for claims at or below a certain amount. This change would improve efficiency in the process and would not result in any inequity to claimants, as the selection would be from a random drawing. FEMA believes this change

will result in a faster assignment of arbitrator to resolve the claim more efficiently consistent with the Act's goal to expeditiously consider and settle claims for injuries resulting from the Fire. FEMA seeks comment on this process. FEMA is also increasing the thresholds associated with the assignment of either one arbitrator or a panel of three arbitrators to reflect inflationary increases since the Cerro Grande regulation was published.¹⁷ Amounts in dispute of \$500,000 or less will be decided by one arbitrator while a panel of three arbitrators will decide amounts in dispute exceeding \$500,000.18 FEMA seeks comment on the increased thresholds.

In paragraph (d), FEMA seeks to modernize the arbitration process by generally offering virtual arbitration hearings to promote efficiency in the process. Additionally, given the scope of the Fire, FEMA is not providing a specific location for any in-person hearing, but rather allowing the Arbitration Administrator the flexibility to select a location in New Mexico for those limited circumstances in which an in-person hearing is held. Decisions will be in writing and provided to the Arbitration Administrator, the claimant, and the Director of the Claims Office under paragraph (e). FEMA seeks comment on these provisions.

Consistent with the Cerro Grande Fire Assistance process, decisions will be rendered no later than 10 days after a hearing is concluded, although the Arbitration Administrator may extend the decision timeline with notice to both the claimant and the Director of the Claims Office. Written arbitration decisions will establish the compensation due to a claimant, if any, and the corresponding rationale. Consistent with the Cerro Grande Fire Assistance arbitration process, the Arbitration Administrator will forward a Release and Certification Form to the claimant with the written decision. Any additional compensation that is awarded as a result of the arbitration will be paid after the signed Release and Certification Form is received.

Paragraphs (f) and (g) are generally consistent with the Cerro Grande Fire Assistance process. If additional compensation is awarded at arbitration, the Arbitration Administrator will forward the decision to the claimant with a Release and Certification Form.

Such compensation will be paid to the claimant after the signed Form is received by the Arbitration Administrator. FEMA reiterates in paragraph (g) that arbitration decisions are not subject to any further appeal or review and are binding on the claimant and on FEMA. Paragraph (i) includes a provision that while the Arbitration Administrator will pay all fees and expenses of the arbitrator or arbitrators assigned, claimants are responsible for any expenses they incur as a result of the arbitration, including travel costs. This update to the Cerro Grande Fire Assistance process ensures fairness by eliminating the provision to allow the parties to jointly agree to pay such fees. FEMA seeks comment on this provision.

4. Section 296.43 Judicial Review

Section 296.43 discusses judicial review of the Administrative Appeal decision, which remains consistent with the Cerro Grande Fire Assistance process and the provisions of the Act. Claimants may seek judicial review in lieu of arbitration if dissatisfied with the outcome of the Administrative Appeal decision. The suit must be filed in the United States District Court for the District of New Mexico within 60 days of a final decision of the Administrator under the Act. Only evidence in the administrative record will be considered by the court. Claimants should be aware that section 104(i)(3) of the Act requires that the court uphold the Administrative Appeals decision if it is supported by substantial evidence on the record considered as a whole.

IV. Regulatory Analysis

A. Administrative Procedure Act (APA)

For the reasons that follow, FEMA is issuing this rule as an interim final rule pursuant to statutory authority under the Act. Specifically, section 104(f)(1) requires FEMA to publish "interim final regulations for the processing and payment of claims under this Act." Further, these regulations must be published "not later than 45 days after the date of enactment." Given Congress' specific authority to issue an interim final rule, the agency is proceeding without advance notice and comment as required under the APA. See 5 U.S.C. 553(b) and (c).

The APA also provides an exception to prior notice and comment for rules of agency organization, procedures, or practice. 5 U.S.C. 553(b)(A). This interim final rule implements the Hermit's Peak/Calf Canyon Fire Assistance Act by detailing how FEMA will process and pay claims under the Act. The majority of the provisions in

¹⁷ Inflationary adjustments have been made based on the Consumer Price Index for All Urban Consumers as published by the U.S. Department of Labor. See generally https://www.bls.gov/data/ inflation_calculator.htm.

 $^{^{18}\, \}rm The$ Cerro Grande Fire Assistance regulations at 44 CFR 295.42(d) set the threshold at \$300,000.

this interim final rule are procedural because they create the procedural framework through which FEMA is able to efficiently implement a claims process to compensate victims of the Fire. The rule details how a claimant may seek compensation through a claims process with the Office of Hermit's Peak/Calf Canyon Fire Claims ("Claims Office") from initiating a claim with a Notice of Loss through appeal and arbitration or judicial review of an Authorized Official's determination of the claim. This interim final rule provides the voluntary process by which an Injured Party may file a claim under the Act. Injured Persons may seek compensation through the Federal Tort Claims Act or a civil action in lieu of filing a claim under the Act. This interim final rule sets out the agency's procedure for how to voluntarily file a claim. Since this rule is procedural in nature, it is excepted from the notice and comment requirements under 5 U.S.C. 553(b)(A).

Consistent with Congress' direction in section 104(f)(1) of the Act that FEMA publish "interim final regulations for the processing and payment of claims under [the] Act," good cause exists pursuant to 5 U.S.C. 553(b)(B) as it would be impracticable and contrary to the public interest to require notice and comment rulemaking in this instance. Potential claimants are currently without (and awaiting) compensation for injuries they suffered due to a massive wildfire. They need to rebuild as soon as possible to regain normalcy, reduce erosion, and restore land health.¹⁹ The sooner the federal government can compensate them, the sooner they can begin the process of rebuilding and recovery. And so FEMA must establish the relevant regulatory framework without delay, so as to be able to respond expeditiously and without unnecessary confusion regarding the applicable procedures for claimants under the Act. Section 102(b)(2) lists as one of the two purposes of the Act to "provide for the expeditious consideration and settlement of claims" for the injuries suffered as a result of the Fire. The Fire constitutes the largest wildfire in New Mexico history.²⁰ Over 340,000 acres of

forest burned during the Fire and over half of the land impacted by the Fire consisted of privately-owned land, with just under 200,000 total acres burned.²¹ At least 160 homes and a total of over 900 structures were destroyed during the Fire.²² Despite containment, the impact of the Fire continues to be felt in the impacted areas, causing flooding and setting off a drinking water crisis.23 The higher burn severity of soil on private lands increases the likelihood of flooding and mudslide impacts on those areas. Residents in the areas of the Fire have already suffered significant damage from flooding, including washed out roads and buildings, drowned pastures, and burned debris moved downstream.²⁴ In addition, as noted above, Congress explicitly mandated in section 104(f)(1) of the Act that FEMA promulgate these regulations expeditiously as interim final regulations, a factor that supports a finding of "good cause." Pursuant to section 104(f)(1) of the Act, consistent with 5 U.S.C. 553(b)(B), and for the reasons stated above, FEMA therefore will dispense with prior public notice and the opportunity to comment on this rule before finalizing this rule and to make this interim final rule effective immediately upon publication.

Based on the discussion above, FEMA further finds there is good cause, under 5 U.S.C. 553(d)(3), not to require a 30-day delayed effective date for this rulemaking because delaying implementation of the rule by 30 days is contrary to the goal of the statutory requirement to issue an interim final rule within 45 days after the Act's enactment, and delay would further negatively impact claimants seeking compensation through the Act. While

FEMA believes the agency has the statutory authority pursuant to section 104(f)(1) of the Act and 5 U.S.C. 553 (b)(A), 553(b)(B), and 553(d)(3) to issue the rule without advance notice and comment and with an immediate effective date, FEMA is interested in the views of the public and requests comment on all aspects of the interim final rule.

B. Executive Order 12866, Regulatory Planning and Review and Executive Order 13563, Improving Regulation and Regulatory Review

Executive Order 12866 (Regulatory Planning and Review) and Executive Order 13563 (Improving Regulation and Regulatory Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a "significant regulatory action" that is economically significant, under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

In this rule, FEMA is establishing the process by which claimants who were injured as a result of the Fire may apply for compensation under the Act. Affected State, local, and Tribal governments, private sector businesses, not-for-profit organizations, and individuals and households will be eligible to apply for compensation. This rule will result in costs to claimants for time to apply for and substantiate a claim, and for FEMA to process and adjudicate claims. Claimants will submit a Notice of Loss to FEMA, meet with a FEMA Claims Reviewer, obtain the documentation needed to substantiate claims, sign a Proof of Loss, and complete and return a Release and Certification Form. Additionally, affected insurance companies can submit a subrogation notice of loss for possible compensation under the Act. Claimants who disagree with FEMA's evaluation of the claim may also incur costs to appeal the determination. FEMA estimates over 57,000 claimants will seek compensation under the Act, totaling between 1.3 and 1.6 million burden hours over the two-year period,

¹⁹ See New Mexico Forest and Watershed Restoration Institute, "Hermit's Peak and Calf Canyon Fire: The largest wildfire in New Mexico's recorded history and its lasting impacts" Aug. 24, 2022 found at https://storymaps.arcgis.com/stories/ d48e2171175f4aa4b5613c2d11875653 (last accessed Sept. 27, 2022).

²⁰ See Bryan Pietsch and Jason Samenow, "New Mexico blaze is now largest wildfire in state history," The Washington Post, May 17, 2022 found at https://www.washingtonpost.come/nation/2022/

^{05/17/}calf-canyon-hermits-peak-fire-new-mexico/ (last accessed Sept. 15, 2022).

²¹ See New Mexico Forest and Watershed Restoration Institute, "Hermit's Peak and Calf Canyon Fire: The largest wildfire in New Mexico's recorded history and its lasting impacts" Aug. 24, 2022 found at https://storymaps.arcgis.com/stories/ d48e2171175f4aa4b5613c2d11875653 (last accessed Sept. 27, 2022).

²² Id.

²³ See Jordan Honeycutt, "Rain brings flash flooding to Hermits Peak Calf Canyon burn scar," KRQE, July 13, 2022 found at https://www.krqe.com/news/new-mexico/rain-brings-flash-flooding-to-hermits-peak-calf-canyon-burn-scar/ (last accessed Sept. 27, 2022), and Simon Romero, "How New Mexico's Largest Wildfire Set Off a Drinking Water Crisis," The New York Times, Sept. 26, 2022 found at https://www.nytimes.com/2022/09/26/us/new-mexico-las-vegas-fire-water.html (last accessed Sept. 27, 2022).

²⁴ See New Mexico Forest and Watershed Restoration Institute, "Hermit's Peak and Calf Canyon Fire: The largest wildfire in New Mexico's recorded history and its lasting impacts" Aug. 24, 2022 found at https://storymaps.arcgis.com/stories/ d48e2171175f4aa4b5613c2d11875653 (last accessed Sept. 27, 2022).

depending on if all applicants submit all forms. 25

The rule will result in additional transfer payments from FEMA to victims for the settlement of claims for injuries resulting from the Fire. Injuries may include property, business and/or financial losses. Congress appropriated \$2.5 billion to provide for the expeditious consideration and settlement of these claims.26 The maximum total economic impact of this rule, therefore, is \$2.5 billion (assuming that all funds awarded will be expended). These funds are for the settlement of actual compensatory damages measured by injuries suffered, FEMA's administration of the program, and DHS OIG oversight.27 However, without knowing the dollar amount of claims that will be filed for these injuries, it is impossible to predict the amount of the economic impact of this rule with any precision.

The Act requires claims must be submitted no later than two years after publication of this interim final rule or November 14, 2024.²⁸ The Act requires that FEMA determine and fix the amount to be paid for a claim within 180 days after a claim is submitted.²⁹ Although the impact of the rule could be spread over multiple years as claims are received, processed, and paid, the total economic effects of a specific payment would only occur once, rather than annually.

This rule will provide distributional benefits to victims of the Fire. FEMA has provided immediate assistance under the Robert T. Stafford Disaster Relief and Emergency Assistance Act to those eligible for public and individual assistance pursuant to the President's declaration of a major disaster on May 4, 2022. The additional compensation from the Act will more fully compensate victims and allow affected State, local and Tribal governments, businesses, organizations, and individuals to rebuild.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 605(b)) applies only to rules for which an agency publishes a general notice of proposed rulemaking pursuant to 5 U.S.C. 553(b). As discussed

previously, FEMA is not issuing a notice of proposed rulemaking. Accordingly, the RFA's requirements do not apply.

D. Unfunded Mandates Reform Act of 1995

FEMA has not issued a notice of proposed rulemaking for this regulatory action; therefore, the written statement provisions of the Unfunded Mandates Reform Act of 1995, as amended, do not apply to this regulatory action.

E. Paperwork Reduction Act of 1995

This rule contains information collections necessary to support FEMA's implementation of the Act. The Notice of Loss and Proof of Loss forms are a new collection (OMB Control Number 1660–NW162) submitted under OMB's emergency clearance procedures to allow FEMA to begin accepting claims immediately after publication of this interim final rule. Additionally, FEMA will seek public comments on the collection through the normal clearance process.

F. Privacy Act

Under the Privacy Act of 1974, 5 U.S.C. 552a, an agency must determine whether implementation of a regulation will result in a system of records. A "record" is any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, his/her education, financial transactions, medical history, and criminal or employment history and that contains his/her name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or a photograph. See 5 U.S.C. 552a(a)(4). A "system of records" is a group of records under the control of an agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. An agency cannot disclose any record which is contained in a system of records except by following specific procedures.

In accordance with DHS policy, FEMA has completed a Privacy Threshold Analysis (PTA) for this rule. DHS has determined that this rulemaking does not affect the 1660–NW162 OMB Control Number's compliance with the E-Government Act of 2002 or the Privacy Act of 1974, as amended. Specifically, DHS has concluded that the 1660–NW162 OMB Control Number is covered by the DHS/FEMA/PIA–044 National Fire Incident Reporting Systems (NFIRS) Privacy Impact Assessment (PIA) and the DHS/

FEMA/PIA-049 Individual Assistance (IA) Program PIA. Additionally, DHS has decided that the 1660–NW162 OMB Control Number is covered by DHS/FEMA-008 Disaster Recovery Assistance Files, 87 FR 7852 (Feb. 10, 2022), DHS/ALL-004 General Information Technology Access Account Records System, 77 FR 70792 (Nov. 27, 2012), and DHS/ALL-013 Department of Homeland Security Claims Records, 73 FR 63987 (Oct. 28, 2008) System of Records Notices (SORNs).

G. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments," 65 FR 67249, November 9, 2000, applies to agency regulations that have Tribal implications, that is, regulations that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Under this Executive Order, to the extent practicable and permitted by law, no agency shall promulgate any regulation that has Tribal implications, that imposes substantial direct compliance costs on Indian Tribal governments, and that is not required by statute, unless funds necessary to pay the direct costs incurred by the Indian Tribal government or the Tribe in complying with the regulation are provided by the Federal Government, or the agency consults with Tribal officials.

FEMA has reviewed this interim final rule under Executive Order 13175 and has determined that this interim final rule may have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. FEMA will enter into consultation with the Indian Tribes that have been impacted by the Fire and whose Tribal entities or Tribal members have been impacted by the Fire during the public comment period of this rulemaking.

H. Executive Order 13132, Federalism

Executive Order 13132, "Federalism," 64 FR 43255, August 10, 1999, sets forth principles and criteria that agencies must adhere to in formulating and implementing policies that have federalism implications, that is, regulations that have "substantial direct effects on the States, on the relationship

²⁵ Not all Claimants will submit a Mitigation Assistance or a Subrogation Notice and Proof of Loss Form. FEMA estimates that 57,450 applicants will incur between 22.75 and 27.75 burden hours, depending on the Forms they submit.

²⁶ Division A of Public Law 117–180, *136 Stat.* 2144 (2022).

²⁷ Id.

²⁸ Id.

²⁹ Division G of Public Law 117–180, *136 Stat.* 2114 (2022).

between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." Federal agencies must closely examine the statutory authority supporting any action that would limit the policymaking discretion of the States, and to the extent practicable, must consult with State and local officials before implementing any such action.

FEMA has determined that this rulemaking does 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, and therefore does not have federalism implications as defined by the Executive Order. FEMA, however, seeks comment on this determination from any States that have been impacted by the Fire and who seek assistance pursuant to the Act.

I. National Environmental Policy Act of 1969 (NEPA)

Under the National Environmental Policy Act of 1969 (NEPA), as amended, 42 U.S.C. 4321 et seq., an agency must prepare an environmental assessment or environmental impact statement for any rulemaking that significantly affects the quality of the human environment. FEMA has determined that this rulemaking does not significantly affect the quality of the human environment and consequently has not prepared an environmental assessment or environmental impact statement.

Rulemaking is a major Federal action subject to NEPA. Categorical exclusion A3 included in the list of exclusion categories at Department of Homeland Security Instruction Manual 023-01-001-01, Revision 01, Implementation of the National Environmental Policy Act, Appendix A, issued November 6, 2014, covers the promulgation of rules, issuance of rulings or interpretations, and the development and publication of policies, orders, directives, notices, procedures, manuals, and advisory circulars if they meet certain criteria provided in A3(a)-(f). This interim final rule meets Categorical Exclusion A3(a), "[t]hose of a strictly administrative or procedural nature," and A3(b), "[t]hose that implement, without substantive change, statutory or regulatory requirements." FEMA has determined that there are no extraordinary circumstances that prevent the use of this categorical exclusion for this rulemaking action.

J. Executive Order 12898 Environmental Justice

Under Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," 59 FR 7629 (Feb. 16, 1994), as amended by Executive Order 12948, 60 FR 6381, (Feb. 1, 1995), FEMA incorporates environmental justice into its policies and programs. The Executive Order requires each Federal agency to conduct its programs, policies, and activities that substantially affect human health or the environment in a manner that ensures that those programs, policies, and activities do not have the effect of excluding persons from participation in programs, denying persons the benefits of programs, or subjecting persons to discrimination because of race, color, or national origin.

This rulemaking would not have a disproportionately high or adverse effect on human health or the environment, nor would it exclude persons from participation in FEMA programs, deny persons the benefits of FEMA programs, or subject persons to discrimination because of race, color, or national origin.

K. Congressional Review of Agency Rulemaking

Under the Congressional Review of Agency Rulemaking Act (CRA), 5 U.S.C. 801–808, before a rule can take effect, the Federal agency promulgating the rule must: submit to Congress and to the Government Accountability Office (GAO) a copy of the rule; a concise general statement relating to the rule, including whether it is a major rule; the proposed effective date of the rule; a copy of any cost-benefit analysis; descriptions of the agency's actions under the Regulatory Flexibility Act and the Unfunded Mandates Reform Act; and any other information or statements required by relevant executive orders.

FEMA has submitted this rule to the Congress and to GAO pursuant to the CRA. The Office of Management and Budget has determined that this rule is "economically significant," but FEMA believes this rule is not a "major rule" within the meaning of the CRA. FEMA believes this interim final rule is not subject to the additional review requirements under the CRA given the statutory mandate to issue this interim final rule within 45 days of the Act's enactment under section 104(f) of the Act. This interim final rule is a procedural rule and does not confer any substantive rights, benefits, or obligations but rather only sets out the agency's procedure for how to voluntarily file a claim under the Act.

As such, this interim final rule is a "rule of agency organization, procedure, or practice that does not substantially affect the rights or obligation of nonagency parties" pursuant to 5 U.S.C. 804(3)(C). Finally, even if this interim final rule is considered a "rule" under the CRA, FEMA finds there is good cause to dispense with notice and public comment under 5 U.S.C. 808(2). Notice and public comment are impracticable and contrary to public interest given the Act's requirement for the agency to publish an interim final rule within 45 days of enactment and the Act's purpose to provide expeditious consideration and settlement of claims for victims of the Fire as explained above. Therefore, there is no delay in its effective date under the CRA.

List of Subjects in 44 CFR Part 296

Administrative practice and procedure, Claims, Disaster assistance, Federally affected areas, Indians, Indians—lands, Indians—Tribal government, Organization and functions (Government agencies), Public lands, Reporting and recordkeeping requirements, State and local governments.

For the reasons discussed in the preamble, the Federal Emergency Management Agency (FEMA) amends subchapter E of title 44 of the Code of Federal Regulations by revising the subchapter heading and adding part 296 to read as follows:

SUBCHAPTER E—FIRE ASSISTANCE

PART 296—HERMIT'S PEAK/CALF CANYON FIRE ASSISTANCE

Sec.

Subpart A—General

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Authority: Pub. L. 117–180, 136 Stat. 2114, 2168; Homeland Security Act of 2002, 6 U.S.C. 101 *et seq.*

Subpart A—General

§ 296.1 Purpose.

This part implements the Hermit's Peak/Calf Canyon Fire Assistance Act (Act), Division G of Public Law 117–180, 136 Stat. 2114, 2168, which requires the Federal Emergency Management Agency (FEMA) to establish the Office of Hermit's Peak/Calf Canyon Fire Claims ("Claims Office") to receive, evaluate, process, and pay actual compensatory damages for injuries suffered from the Hermit's Peak/Calf Canyon Fire.

§ 296.2 Policy.

It is our policy to provide for the expeditious resolution of damage claims through a process that is administered with sensitivity to the burdens placed upon claimants by the Hermit's Peak/Calf Canyon Fire.

§ 296.3 Information and assistance.

Information and assistance concerning the Act is available from the Claims Office, Federal Emergency Management Agency online at http://www.fema.gov/hermits-peak.

§ 296.4 Definitions.

Administrative Appeal means an appeal of the Authorized Official's Determination to the Director of the Claims Office in accordance with the provisions of Subpart E of this part.

Administrative Record means all information submitted by the claimant and all information collected by FEMA concerning the claim, which is used to evaluate the claim and to formulate the Authorized Official's Determination. It also means all information that is submitted by the claimant or FEMA in an Administrative Appeal and the decision of the Administrative Appeal. It excludes the opinions, memoranda and work papers of FEMA attorneys and

drafts of documents prepared by Claims Office personnel and contractors.

Administrator means the Administrator of the Federal Emergency Management Agency.

Arbitration Administrator means the FEMA official responsible for administering arbitration procedures to resolve disputes regarding a claim. Contact information for the Arbitration Administrator can be found online at http://www.fema.gov/hermits-peak.

Authorized Official means an employee of the United States who is delegated with authority by the Director of the Claims Office to render binding determinations on claims and to determine compensation due to claimants under the Act.

Authorized Official's Determination means a report signed by an Authorized Official and mailed to the claimant evaluating each element of the claim as stated in the Proof of Loss and determining the compensation, if any, due to the claimant.

Claimant means a person who has filed a Notice of Loss under the Act.

Claims Office means the Office of Hermit's Peak/Calf Canyon Fire Claims.

Claims Reviewer means an employee of the United States or a Claims Office contractor or subcontractor who is authorized by the Director of the Claims Office to review and evaluate claims submitted under the Act.

Days means calendar days, including weekends and holidays.

Director means an Independent Claims Manager appointed by the Administrator who will serve as the Director of the Claims Office.

Good Cause, for purposes of extending the deadline for filing, supplementing a claim, or reopening a claim includes, but is not limited to: instances where a claimant, through no fault of their own, may not be able to access needed documentation in time to submit a claim or transmit relevant information or data; or where damage is found after a claim has been submitted; or other instances in which the Director of the Claims Office, in their discretion, determines that an undue hardship or change in circumstances on the claimant warrants an extension of a deadline or the supplementation or reopening of existing claims.

Hermit's Peak/Calf Canyon Fire

- (1) The fire resulting from the initiation by the U.S. Forest Service of a prescribed burn in the Santa Fe National Forest in San Miguel County, New Mexico on April 6, 2022;
- (2) The pile burn holdover resulting from the prescribed burn by the U.S.

Forest Services which reemerged on April 19, 2022; and

(3) The merger of the two fires described in paragraphs (1) and (2) of this definition, reported as the Hermit's Peak Fire or the Hermit's Peak Fire/Calf Canyon Fire.

Household means a group of people, related or unrelated, who live together on a continuous basis and does not include members of an extended family who do not regularly and continuously cohabit.

Household Including Tribal Members means a Household that existed on April 6, 2022, which included one or more Tribal Members as continuous residents.

Indian Tribe means the recognized governing body of any Indian or Alaska Native Tribe, band, nation, pueblo, village, community, component band, or components reservation individually identified (including parenthetically) in the list published most recently as of September 30, 2022, pursuant to section 104 of the Federally Recognized Indian Tribe List Act of 1994.

Individual Assistance means the FEMA program established under Subchapter IV of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended, 42 U.S.C. 5121, et seq., which provides assistance to individuals and families adversely affected by a major disaster or an emergency.

Injured Person means an individual, regardless of citizenship or alien status; or an Indian Tribe, Tribal corporation, corporation, partnership, company, association, county, township, city, State, school district, or other non-Federal entity that suffered injury resulting from the Hermit's Peak/Calf Canyon Fire. The term Injured Person includes an Indian Tribe with respect to any claim relating to property or natural resources held in trust for the Indian Tribe by the United States. Lenders holding mortgages or security interests on property affected by the Hermit's Peak/Calf Canyon Fire and lien holders are not an "Injured Person" for purposes

Injury means "injury or loss of property, or personal injury or death," as used in the Federal Tort Claims Act, 28 U.S.C. 1346(b)(1).

of the Act.

Notice of Loss means a form supplied by the Claims Office through which an Injured Person or Subrogee makes a claim for possible compensation under the Act.

Proof of Loss means a statement attesting to the nature and extent of the claimant's injuries.

Public Assistance Program means the FEMA program established under

Subchapter IV of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended, 42 U.S.C. 5121, et seq., which provides grants to States, local governments, Indian Tribes and private nonprofit organizations for emergency measures and repair, restoration, and replacement of damaged facilities.

Release and Certification Form means a document in the manner prescribed by section 104(e) of the Act that all claimants who have received or are awarded compensatory damages under the Act must execute and return to the Claims Office as required by § 296.30(c).

Subsistence Resources means food and other items obtained through hunting, fishing, firewood gathering, timbering, grazing or agricultural activities undertaken by the claimant without financial remuneration, on land damaged by the Hermit's Peak/Calf Canyon Fire.

Subrogee means an insurer or other third party that has paid to a claimant compensation for Injury and is subrogated to any right that the claimant has to receive payment under the Act.

Tribal Member means an enrolled member of an Indian Tribe.

§ 296.5 Overview of the claims process.

(a) The Act is intended to provide persons who suffered Injury from the Hermit's Peak/Calf Canyon Fire with a simple, expedited process to seek compensation from the United States. This section provides a brief explanation of the claims process for claims other than subrogation claims. It is not intended to supersede the more specific regulations that follow and explain the claims process in greater detail. To obtain compensation under the Act, an Injured Person must submit all Hermit's Peak/Calf Canyon Fire related claims against the United States or any employee, officer, or agency of the United States to the FEMA Claims Office. An Injured Person who elects to accept an award under the Act is barred from accepting an award pursuant to a claim under the Federal Tort Claims Act or a civil action against the United States or any employee, officer, or agency of the United States arising out of or relating to the same subject matter. Judicial review of FEMA decisions under the Act is available.

(b) The first step in the process is to file a Notice of Loss with the Claims Office. The Claims Office will provide the claimant with a written acknowledgement that the claim has been filed and a claim number.

(c) Shortly thereafter, a Claims Reviewer will contact the claimant to review the claim. Claims Reviewer will

help the claimant formulate a strategy for obtaining any necessary documentation or other support. This assistance does not relieve the claimant of their responsibility for establishing all elements of the injuries and the compensatory damages that are sought, including that the Hermit's Peak/Calf Canyon Fire caused the injuries. After the claimant has had an opportunity to discuss the claim with the Claims Reviewer, a Proof of Loss will be presented to the claimant for signature. After any necessary documentation has been obtained and the claim has been fully evaluated, the Claims Reviewer will submit a report to the Authorized Official. The Claims Reviewer is responsible for providing an objective evaluation of the claim to the Authorized Official.

(d) The Authorized Official will review the report and determine whether compensation is due to the claimant. The claimant will be notified in writing of the Authorized Official's determination. If the claimant is satisfied with the decision, payment will be made after the claimant returns a completed Release and Certification Form. If the claimant is dissatisfied with the Authorized Official's determination, an administrative appeal may be filed with the Director of the Claims Office. If the claimant remains dissatisfied after the appeal is decided, the dispute may be resolved through binding arbitration or heard in the United States District Court for the District of New Mexico.

Subpart B—Bringing a Claim Under the Hermit's Peak/Calf Canyon Fire Assistance Act

§ 296.10 Filing a claim under the Hermit's Peak/Calf Canyon Fire Assistance Act.

- (a) Any Injured Person may bring a claim under the Act by filing a Notice of Loss. A claim submitted on any form other than a Notice of Loss will not be accepted. The claimant must provide a brief description of each injury on the Notice of Loss.
- (b) A single Notice of Loss may be submitted on behalf of a household containing Injured Persons provided that all Injured Persons on whose behalf the claim is presented are identified.
- (c) The Notice of Loss must be signed by each claimant, if the claimant is an individual, or by a duly authorized legal representative of each claimant, if the claimant is an entity or an individual who lacks the legal capacity to sign the Notice of Loss. If one is signing a Notice of Loss as the legal representative of a claimant, the signer must disclose their relationship to the claimant. FEMA may

require a legal representative to submit evidence of their authority to act.

- (d) The Claims Office will provide Notice of Loss forms through the mail, electronically, in person at the Claims Office or by telephone request. The Notice of Loss form can also be downloaded from the internet at http://www.fema.gov/hermits-peak.
- (e) A Notice of Loss may be filed with the Claims Office by mail, electronically, or in person. Details regarding the filing process can be found at http://www.fema.gov/hermitspeak.
- (f) A Notice of Loss that is completed and properly signed is deemed to be filed on the date it is received and acknowledged by the Claims Office.

§ 296.11 Deadline for notifying FEMA of injuries.

The deadline for filing a Notice of Loss is November 14, 2024. Except as provided in § 296.35 with respect to a request to reopen a claim, an injury that has not been described: on a Notice of Loss, on a supplement to a Notice of Loss or a request to supplement a Notice of Loss under § 296.34 received by the Claims Office on or before November 14, 2024 cannot be compensated under the Act. The Act establishes this deadline and does not provide any extensions of the filing deadline.

§ 296.12 Election of remedies.

- (a) An Injured Person who accepts an award under the Act waives the right to pursue all claims for injuries arising out of or relating to the same subject matter against the United States or any employee, officer, or agency of the United States through the Federal Tort Claims Act or a civil action authorized by any other provision of law.
- (b) An Injured Person who accepts an award through a Federal Tort Claims Act claim or a civil action against the United States or any employee, officer, or agency of the United States relating to the Hermit's Peak/Calf Canyon Fire waives the right to pursue any claim arising out of or relating to the same subject matter under the Act.

§ 296.13 Subrogation.

An insurer or other third party with the rights of a subrogee, who has compensated an injured person for Hermit's Peak/Calf Canyon Fire related injuries, may file a Notice of Loss under the Act for the subrogated claim. A subrogee may file a Notice of Loss without regard to whether the Injured Person who received payment from the subrogee filed a Notice of Loss. A Subrogation Notice of Loss should be filed after the subrogee has made all

payments that it believes the Injured Person is entitled to receive for Hermit's Peak/Calf Canyon Fire related injuries under the terms of the insurance policy or other agreement between the subrogee and the Injured Person, but not later than November 14, 2024. By filing a Notice of Loss for any subrogated claim, the subrogee elects the Act as its exclusive remedy against the United States or any employee, officer, or agency of the United States for all subrogated claims arising out of the Hermit's Peak/Calf Canyon Fire. Subrogation claims must be made on a Notice of Loss form furnished by the Claims Office.

§ 296.14 Assignments.

Assignment of claims and the right to receive compensation for claims under the Act is prohibited and will not be recognized by FEMA.

Subpart C—Compensation Available Under the Hermit's Peak/Calf Canyon Fire Assistance Act

§ 296.20 Prerequisite to compensation.

In order to receive compensation under the Act, a claimant must be an Injured Person who suffered an injury as a result of the Hermit's Peak/Calf Canyon Fire and sustained damages.

§ 296.21 Allowable damages.

- (a) Allowable damages. The Act provides for the payment of actual compensatory damages for Injury or loss of property, business loss, and financial loss. The laws of the State of New Mexico will apply to the calculation of damages. Damages must be reasonable in amount.
- (b) Exclusions. Punitive damages, statutory damages under section 30–32– 4 of the New Mexico Statutes Annotated (2019), interest on claims, attorney's fees and agents' fees incurred in prosecuting a claim under the Act or an insurance policy, and adjusting costs incurred by an insurer or other third party with the rights of a subrogee that may be owed by a claimant as a consequence of receiving an award are not recoverable from FEMA. The cost to a claimant of prosecuting a claim under the Act does not constitute compensatory damages and is not recoverable from FEMA, except as provided in § 296.31(b).
- (c) Loss of property. Compensatory damages may be awarded for an uninsured or underinsured property loss, a decrease in the value of real property, damage to physical infrastructure, cost resulting from lost subsistence, cost of reforestation or revegetation not covered by any other

Federal program, and any other loss that the Administrator determines to be appropriate for inclusion as a loss of property.

(1) Real property and contents. Compensatory damages for the damage or destruction of real property and its contents may include the reasonable cost of reconstruction of a structure comparable in design, construction materials, size, and improvements, taking into account post-fire construction costs in the community in which the structure existed before the fire and current building codes and standards. Compensatory damages may also include the cost of removing debris and burned trees, including hazardous materials or soils, stabilizing the land, replacing contents, and compensation for any decrease in the value of land on which the structure sat pursuant to paragraph (c)(3) of this section.

(2) Reforestation and revegetation. Compensation for the replacement of destroyed trees and other landscaping will not exceed 25 percent of the prefire value of the structure and lot.

- (3) Decrease in the value of real property. Compensatory damages may be awarded for a decrease in the value of real property that a claimant owned before the Hermit's Peak/Calf Canyon Fire if:
- (i) The claimant sells the real property in a good faith, arm's length transaction that is closed no later than November 14, 2024 and realizes a loss in the prefire value; or
- (ii) The claimant can establish that the value of the real property was permanently diminished as a result of the Hermit's Peak/Calf Canyon Fire.
- (4) Subsistence. Compensatory damages will be awarded for lost Subsistence Resources.
- (i) FEMA may reimburse an injured party for the reasonable cost of replacing Subsistence Resources customarily and traditionally used by the claimant on or before April 6, 2022, but no longer available to the claimant as a result of the Hermit's Peak/Calf Canyon Fire. For each category of Subsistence Resources, the claimant must elect to receive compensatory damages either for the increased cost of obtaining Subsistence Resources from lands not damaged by the Hermit's Peak/Calf Canyon Fire or for the cost of procuring substitute resources in the cash economy.
- (ii) FEMA may consider evidence submitted by claimants, Indian Tribes, and other knowledgeable sources in determining the nature and extent of a claimant's subsistence uses.
- (iii) Compensatory damages for subsistence losses will be paid for the period between April 6, 2022 and the

date when Subsistence Resources can reasonably be expected to return to the level of availability that existed before the Hermit's Peak/Calf Canyon Fire. FEMA may rely upon the advice of experts in making this determination.

(iv) Long-term damage awards for subsistence resources will be made to claimants in the form of lump sum cash

payments.

- (d) Business loss. Compensatory damages may be awarded for damage to tangible assets or inventory, including timber, crops, and other natural resources; business interruption losses; overhead costs; employee wages for work not performed; loss of business net income; and any other loss that the Administrator determines to be appropriate for inclusion as a business loss.
- (e) Financial loss. Compensatory damages may be awarded for increased mortgage interest costs, insurance deductibles, temporary living or relocation expenses, lost wages or personal income, emergency staffing expenses, debris removal and other cleanup costs, costs of reasonable heightened risk reduction, premiums for flood insurance, and any other loss that the Administrator determines to be appropriate for inclusion as financial loss.
- (1) Recovery loans. FEMA will reimburse claimants awarded compensation under the Act for interest paid on loans, including Small Business Administration disaster loans obtained after April 6, 2022 for damages resulting from the Fire. Interest will be reimbursed for the period beginning on the date that the loan was taken out and ending on the date when the claimant receives a compensation award (other than a partial payment). Claimants are required to use the proceeds of their compensation award to repay Small Business Administration disaster loans. FEMA will cooperate with the Small Business Administration to formulate procedures for assuring that claimants repay Small Business Administration disaster loans contemporaneously with the receipt of their compensation award.
- (2) Flood insurance. FEMA will reimburse claimants for flood insurance premiums to be paid on or before May 31, 2024 if, as a result of the Hermit's Peak/Calf Canyon Fire, a claimant who was not required to purchase flood insurance before the Hermit's Peak/Calf Canyon Fire is required to purchase flood insurance or the claimant did not maintain flood insurance before the Fire but purchased flood insurance after the Fire due to fear of heightened flood risk. Alternatively, FEMA may provide flood

insurance to such claimants directly through a group or blanket policy.

(3) Out of pocket expenses for treatment of mental health conditions. FEMA may reimburse an individual claimant for reasonable out of pocket expenses incurred for treatment of a mental health condition rendered by a licensed mental health professional, which condition resulted from the Hermit's Peak/Calf Canyon Fire. FEMA will not reimburse for treatment rendered after April 6, 2024.

(4) Donations. FEMA will compensate claimants for the cost of merchandise, use of equipment or other non-personal services, directly or indirectly donated to survivors of the Hermit's Peak/Calf Canyon Fire not later than September 20, 2022. Donations will be valued at

cost,

- (5) Heightened Risk Reduction. FEMA will reimburse claimants for the costs incurred to implement reasonable measures necessary to reduce risks from natural hazards heightened by the Hermit's Peak/Calf Canyon Fire to the level of risk prevailing before the Hermit's Peak/Calf Canyon Fire. Such measures may include, for example, risk reduction projects that reduce an increased risk from flooding, mudslides, and landslides in and around burn scars. Compensation under this section may not exceed 25 percent of the higher of payments from all sources (i.e., the Act, insurance proceeds, FEMA assistance under the Stafford Act) for damage to the structure and lot, or the pre-fire value of the structure and lot. Claimants seeking compensation for heightened risk reduction must include the claim in their Notice of Loss by November 14, 2024 or an amended Notice of Loss filed no later than November 14, 2025. Claimants should take into account current building codes and standards and must complete the risk reduction project for which they receive compensation.
- (f) Insurance and other benefits. The Act allows FEMA to compensate Injured Persons only for damages not paid, or will not be paid, by insurance or other third-party payments or settlements.
- (1) *Însurance*. Claimants who carry insurance will be required to disclose the name of the insurer(s) and the nature of the insurance and provide the Claims Office with such insurance documentation as the Claims Office reasonably requests.
- (2) Coordination with FEMA's Public Assistance Program. Injured Persons eligible for disaster assistance under FEMA's Public Assistance Program are expected to apply for all available assistance. Pursuant to the Act, the Federal share of the costs for Public

- Assistance projects is 100 percent. Compensation will not be awarded under the Act for injuries or costs that are eligible under the Public Assistance Program.
- (3) Benefits provided by FEMA's Individual Assistance program.
 Compensation under the Act will not be awarded for injuries or costs that have been reimbursed under the Federal Assistance to Individual and Households Program or any other FEMA Individual Assistance Program.
- (4) Worker's compensation claims. Individuals who have suffered injuries that are compensable under State or Federal worker's compensation laws must apply for all benefits available under such laws.
- (5) Benefits provided by nongovernmental organizations and individuals. Gifts or donations made to a claimant by a non-governmental organization or an individual, other than wages paid by the claimant's employer or insurance payments, will be disregarded in evaluating claims and need not be disclosed to the Claims Office by claimants.

Subpart D—Claims Evaluation

§ 296.30 Establishing injuries and damages.

- (a) Burden of proof. The burden of proving injuries and damages rests with the claimant. A claimant may submit for the Administrative Record a statement explaining why the claimant believes that the injuries and damages are compensable and any documentary evidence supporting the claim. Claimants will provide documentation, which is reasonably available, including photographs and video, to corroborate the nature, extent, and value of their injuries and/or to execute affidavits in a form established by the Claims Office. FEMA may compensate a claimant for an injury in the absence of supporting documentation, in its discretion, on the strength of an affidavit or Proof of Loss executed by the claimant, if documentary evidence substantiating the injury is not reasonably available. FEMA may also require an inspection of real property. FEMA may request that a business claimant execute an affidavit, which states that the claimant will provide documentary evidence, including but not limited to income tax returns, if requested by the DHS Office of the Inspector General or the Government Accountability Office during an audit of the claim.
- (b) *Proof of Loss.* All claimants are required to attest to the nature and extent of each injury for which compensation is sought in the Proof of

- Loss. The Proof of Loss, which will be in a form specified by the Claims Office, must be signed by the claimant or the claimant's legal representative if the claimant is not an individual or is an individual who lacks the legal capacity to execute the Proof of Loss. The Proof of Loss must be signed under penalty of perjury. Non-subrogation claimants should submit a signed Proof of Loss to the Claims Office not later than 150 days after the date when the Notice of Loss was submitted. This deadline may be extended at the discretion of the Director of the Claims Office for good cause. If a non-subrogation claimant fails to submit a signed Proof of Loss within the timeframes set forth in this section and does not obtain an extension from the Director of the Claims Office, the Claims Office may administratively close the claim and require the claimant to repay any partial payments made on the claim. Subrogation claimants will submit the Proof of Loss contemporaneously with filing the Notice of Loss.
- (c) Release and Certification Form. All claimants who receive compensation under the Act are required to sign a Release and Certification Form, including for partial payments under § 296.33. The Release and Certification Form must be executed by the claimant or the claimant's legal representative if the claimant is an entity or lacks the legal capacity to execute the Release and Certification Form. A Release and Certification Form must be received by the Claims Office before the Claims Office provides payment on the claim. The United States will not attempt to recover compensatory damages paid to a claimant who has executed and returned a Release and Certification Form within the periods provided above, except in the case of fraud or misrepresentation by the claimant or the claimant's representative, failure of the claimant to cooperate with an audit as required by § 296.36 or a material mistake by FEMA.
- (d) Authority to settle or compromise claims. Notwithstanding any other provision of this part, the Director of the Claims Office may extend an offer to settle or compromise a claim or any portion of a claim at any time during the process outlined in this part, which if accepted by the claimant will be binding on the claimant and on the United States, except that the United States may recover funds improperly paid to a claimant due to fraud or misrepresentation on the part of the claimant or the claimant's representative, a material mistake on FEMA's part or the claimant's failure to

cooperate in an audit as required by § 296.36.

§ 296.31 Reimbursement of claim expenses.

(a) FEMA will reimburse claimants for the reasonable costs they incur in providing documentation requested by the Claims Office. FEMA will also reimburse claimants for the reasonable costs they incur in providing appraisals, or other third-party opinions, requested by the Claims Office. FEMA will not reimburse claimants for the cost of appraisals or other third-party opinions not requested by the Claims Office.

(b) FEMA will provide a lump sum payment for incidental expenses incurred in claims preparation to claimants that are awarded compensatory damages under the Act after a properly executed Release and Certification Form has been returned to the Claims Office. The amount of the lump sum payment will be the greater of \$150 or 5% of the Act's compensatory damages and insurance proceeds recovered by the claimant for Hermit's Peak/Calf Canyon Fire related injuries (not including the lump sum payment or monies reimbursed under the Act for the purchase of flood insurance) but will not exceed \$25,000. Subrogation claimants and claimants whose only Hermit's Peak/Calf Canyon Fire related loss is for flood insurance premiums will not be eligible.

§ 296.32 Determination of compensation due to claimant.

(a) Authorized Official's report. After the Claims Office has evaluated all elements of a claim as stated in the Proof of Loss, the Authorized Official will issue, and provide the claimant with a copy of, the Authorized Official's determination.

(b) Claimant's options upon issuance of the Authorized Official's determination. Not later than 120 days after the date that appears on the Authorized Official's determination, the claimant must either accept the determination by submitting a Release and Certification Form to FEMA and/or initiate an Administrative Appeal in accordance with § 296.41. Claimants must sign the Release and Certification Form to receive payment on their claims (including for partial payments). The claimant will receive payment of compensation awarded by the Authorized Official after FEMA receives the completed Release and Certification Form. If the claimant does not either submit a Release and Certification Form to FEMA or initiate an Administrative Appeal no later than 120 days after the date that appears on the Authorized

Official's determination, the claimant will be conclusively presumed to have accepted the Authorized Official's determination. The Director of the Claims Office may modify the deadlines set forth in this subsection at the request of a claimant for good cause shown.

§ 296.33 Partial payments.

The Claims Office at the request of a claimant may make one or more partial payments on any aspect of a claim that is severable. Receipt by a claimant of a partial payment is contingent on the claimant signing a Release and Certification Form for the severable part of the claim for which partial payment is being made. Acceptance of a partial payment in no way affects a claimant's ability to pursue an Administrative Appeal of the Authorized Official's determination or to pursue other rights afforded by the Act with respect to any portion of a claim for which a Release and Certification Form has not been executed. The Claims Office decision on whether to provide a partial payment cannot be appealed.

§ 296.34 Supplementing claims.

A claimant may amend the Notice of Loss to include additional claims at any time before signing a Proof of Loss. After the claimant has submitted a Proof of Loss and before submission of a Release and Certification Form, a claimant may request that the Director of the Claims Office consider one or more injuries not addressed in the Proof of Loss. The request must be submitted in writing to the Director of the Claims Office and received not later than the deadline for filing an Administrative Appeal under § 296.32 or November 14, 2024, whichever is earlier. It must be supported by the claimant's explanation of why the injury was not previously reported. If good cause is found to consider the additional injury, the Director will determine whether compensation is due to the claimant for the Loss under the Administrative Appeal procedures described in § 296.41.

§ 296.35 Reopening a claim.

The Director of the Claims Office may reopen a claim if requested to do so by the claimant, notwithstanding the submission of the Release and Certification Form, for the limited purpose of considering issues raised by the request to reopen if, not later than November 14, 2025, the claimant desires heightened risk reduction compensation in accordance with § 296.21(e)(5); the claimant closed the sale of a home and wishes to present a claim for decrease in the value of the real property under

§ 296.21(c)(3); the claimant has incurred additional losses under § 296.21(c)(1) as part of a reconstruction in excess of those previously awarded; or the Director of the Claims Office otherwise determines that claimant has demonstrated good cause.

§ 296.36 Access to records.

For purpose of audit and investigation, a claimant will grant the DHS Office of the Inspector General and the Comptroller General of the United States access to any property that is the subject of a claim and to any and all books, documents, papers, and records (including any relevant tax records) maintained by a claimant or under the claimant's control pertaining or relevant to the claim.

§ 296.37 Confidentiality of information.

Confidential information submitted by individual claimants is protected from disclosure to the extent permitted by the Privacy Act. These protections are described in the Privacy Act Notice provided with the Notice of Loss. Other claimants should consult with FEMA concerning the availability of confidentiality protection under exemptions to the Freedom of Information Act and other applicable laws before submitting confidential, proprietary or trade secret information.

Subpart E—Dispute Resolution

§ 296.40 Scope.

This subpart describes a claimant's right to bring an Administrative Appeal in response to the Authorized Official's Determination. It also describes the claimant's right to pursue arbitration or seek judicial review following an Administrative Appeal.

§ 296.41 Administrative appeal.

(a) Notice of appeal. A claimant may request that the Director of the Claims Office review the Authorized Official's determination by written request to the Appeals Docket, Office of Hermit's Peak/Calf Canyon Claims, postmarked or delivered within 120 days after the date that appears on the Authorized Official's determination pursuant to § 296.32. The claimant will submit along with the notice of appeal a statement explaining why the Authorized Official's determination was incorrect. Information regarding where to file can be found at http:// www.fema.gov/hermits-peak.

(b) Acknowledgement of appeal. The Claims Office will acknowledge receipt of an appeal. Following the receipt of a timely filed appeal, the Director of the Claims Office will obtain the Administrative Record from the

Authorized Official and transmit a copy to the claimant.

- (c) Supplemental filings. The claimant may supplement their statement accompanying the appeal and provide any additional documentary evidence supporting the appeal within 60 days after the date when the appeal is filed. The Director of the Claims Office may extend these timeframes or authorize additional filings either on their own initiative or in response to a request by the claimant for good cause shown.
- (d) Admissible evidence. The claimant may rely upon any relevant evidence to support the appeal, regardless of whether the evidence was previously submitted to the Claims Reviewer for consideration by the Authorized Official.
- (e) Obtaining evidence. The Director of the Claims Office may request from the claimant or from the Authorized Official any additional information that is relevant to the issues posed by the appeal in their discretion.
- (f) Conferences. The Director of the Claims Office may schedule a conference to gain a better understanding of the issues or to explore settlement or compromise possibilities. The claimant may also request a conference. Conferences will generally be conducted virtually. In limited circumstances, the Director may convene an in-person conference at a location in New Mexico designated by the Director. A claimant may request that the Director of the Claims Office appoint a mediator at FEMA's expense to facilitate such conferences.
- (g) Hearings. The Director of the Claims Office may exercise the discretion to convene an informal hearing to receive oral testimony from witnesses or experts. The rules under which hearings will be conducted will be established by the Director of the Claims Office and provided to the claimant. Formal rules of evidence applicable to court proceedings will not be used in hearings under this subsection. Hearings will generally be conducted virtually, be transcribed, and the transcript will be entered in the Administrative Record. In limited circumstances, the Director may convene an in-person hearing at a location in New Mexico designated by the Director.
- (h) Decision on appeal. After the allotted time for submission of evidence has passed, the Director of the Claims Office will close the Administrative Record and render a written decision on the Administrative Appeal. The Director of the Claims Office's decision on the Administrative Appeal will constitute

- the final decision of the Administrator of FEMA under sections 104(d)(2)(B) and 104(i)(1) of the Act.
- (i) Claimant's options following appeal. The claimant's concurrence with the decision in the Administrative Appeal will be conclusively presumed unless the claimant initiates arbitration in accordance with § 296.42 or seeks judicial review in accordance with § 296.43. If the claimant concurs with the Director's determination, payment of any additional damages awarded by the Director will be made to the claimant upon receipt of a properly executed Release and Certification Form.

§ 296.42 Arbitration.

- (a) Initiating arbitration. A claimant who is dissatisfied with the outcome of the Administrative Appeal may elect to submit the dispute to a binding arbitration process. A claimant may initiate arbitration by submitting a written request to the Arbitration Administrator for Hermit's Peak/Calf Canvon Claims. Additional information regarding how to submit a written arbitration request can be found at http://www.fema.gov/hermits-peak. The written request for arbitration must be electronically stamped or postmarked no later than 60 days after the date that appears on the Administrative Appeal decision.
- (b) Permissible claims. A claimant may not arbitrate an issue unless it was raised and decided in the Administrative Appeal. Arbitration will be conducted on the evidence in the Administrative Record. Evidence not previously entered into the Administrative Record will not be considered.
- (c) Selection of arbitrator. The Arbitration Administrator will maintain a list of qualified arbitrators who have agreed to serve. The arbitration will be decided by one arbitrator if the amount in dispute is \$500,000 or less and a panel of three arbitrators if the amount in dispute exceeds \$500,000. Arbitrators will be assigned by the Arbitration Administrator through a random drawing.
- (d) Conduct of arbitration. Pursuant to guidelines from the Arbitration Administrator, which will be provided directly to claimants who have filed a request for arbitration, the arbitration process will include an arbitration hearing with consideration of the claimant's written request for arbitration, the Administrative Record, and oral testimony. Hearings will generally be conducted virtually. In limited circumstances, the arbitrator may convene an in-person hearing at a

- location in New Mexico designated by the Arbitration Administrator.
- (e) Decision. After a hearing and reviewing the evidence, the arbitrator(s) will render a written decision and will transmit the decision to the Arbitration Administrator, the claimant, and the Director of the Claims Office. If a panel of three arbitrators conducts the arbitration, at least two of the three arbitrators must sign the decision. The arbitrator(s) should render a decision no later than 10 Days after a hearing is concluded. The Arbitration Administrator may extend the time for a decision with notice to the claimant and the Director of the Claims Office. The decision will establish the compensation due to the claimant, if any, and the reasons therefor.
- (f) Action on arbitration decision. The Arbitration Administrator will forward the arbitration decision to the claimant and, if additional compensation is awarded to the claimant, a Release and Certification Form. Additional compensation awarded in the arbitration will be paid to the claimant after the signed Release and Certification Form is received by the Arbitration Administrator.
- (g) Final decision. The decision of the arbitrator(s) will be final and binding on all parties and will not be subject to any administrative or judicial review. The arbitrator(s) may correct clerical, typographical or computational errors as requested by the Arbitration Administrator.
- (h) Administration of arbitration. The Arbitration Administrator oversees arbitration procedures and will resolve any procedural disputes arising in the course of the arbitration.
- (i) Expenses. The Arbitration Administrator will pay all fees and expenses of the arbitrator(s). The claimant is responsible for any expenses they incur, including travel costs.

§ 296.43 Judicial review.

As an alternative to arbitration, a claimant dissatisfied with the outcome of an Administrative Appeal may seek judicial review of the decision by bringing a civil lawsuit against FEMA in the United States District Court for the District of New Mexico. This lawsuit must be brought within 60 Days of the date that appears on the Administrative Appeal decision. Pursuant to section 104(i) of the Act, the court may only consider evidence in the Administrative Record. The court will uphold FEMA's decision if it is supported by substantial

evidence on the record considered as a whole.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2022–24728 Filed 11–10–22; 8:45 am]

BILLING CODE 9111-68-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 221107-0236; RTID 0648-XC082]

Atlantic Highly Migratory Species; 2023 Atlantic Shark Commercial Fishing Year

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

ACTION: Final rule.

SUMMARY: This final rule adjusts the quotas and retention limits and establishes the opening date for the 2023 fishing year for the Atlantic commercial shark fisheries. Quotas are adjusted as required or allowable based on underharvests from the 2022 fishing year. NMFS establishes the opening date and commercial retention limits to provide, to the extent practicable, fishing opportunities for commercial shark fishermen in all regions and areas. The final measures could affect fishing opportunities for commercial shark fishermen in the northwestern Atlantic Ocean, Gulf of Mexico, and Caribbean Sea.

DATES: This final rule is effective on January 1, 2023. The 2023 Atlantic shark commercial fishing year opens on January 1, 2023 for all species and regions.

ADDRESSES: Electronic copies of this final rule and supporting documents (including the annual Atlantic Highly Migratory Species (HMS) Stock Assessment and Fishery Evaluation Report and the Atlantic HMS Best Scientific Information Available Regional Framework (BSIA Regional

Framework)) are available from the Atlantic HMS Management Division website at https://www.fisheries.noaa.gov/topic/atlantic-highly-migratory-species or by contacting Ann Williamson at ann.williamson@noaa.gov or 301–427–8503.

FOR FURTHER INFORMATION CONTACT: Ann Williamson (ann.williamson@noaa.gov), Guy DuBeck (guy.dubeck@noaa.gov), or Karyl Brewster-Geisz (karyl.brewster-geisz@noaa.gov) at 301–427–8503.

SUPPLEMENTARY INFORMATION:

Background

Atlantic shark fisheries are managed primarily under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 et seq.) and the Atlantic Tunas Convention Act (16 U.S.C. 971 et seq.). The 2006 Consolidated Atlantic HMS Fishery Management Plan (2006 Consolidated HMS FMP) and its amendments are implemented by regulations at 50 CFR part 635.

For the Atlantic commercial shark fisheries, the 2006 Consolidated HMS FMP and its amendments established default commercial shark retention limits, quotas for species and management groups, and accountability measures for underharvests and overharvests. The retention limits, commercial quotas, and accountability measures can be found at 50 CFR 635.24(a), 635.27(b), and 635.28(b). Regulations also include provisions allowing flexible opening dates for the fishing year (§ 635.27(b)(3)) and inseason adjustments to shark trip limits (§ 635.24(a)(8)), which provide management flexibility in furtherance of equitable fishing opportunities, to the extent practicable, for commercial shark fishermen in all regions and areas. In addition, § 635.28(b)(4) lists species and management groups with quotas that are linked. If quotas are linked, when the specified quota threshold for one management group or species is reached and that management group or species is closed, the linked management group or species closes at the same time (§ 635.28(b)(3)). Lastly, pursuant to § 635.27(b)(2), any annual or inseason

adjustments to the base annual commercial overall, regional, or subregional quotas will be published in the **Federal Register**.

Background information about the need to adjust the quotas and retention limits and establish the opening date for the 2023 fishing year for the Atlantic commercial shark fisheries was provided in the proposed rule (87 FR 55379, September 9, 2022) and is not repeated here. The comment period for the proposed rule closed on October 11, 2022. NMFS received 99 written comments, the majority of which were form letter submissions. Summaries of the comments received, and our responses to those comments, are in the Response to Comments section, Similar comments are combined, where appropriate. After reviewing and considering all the public comments received on the proposed rule, NMFS is finalizing the rule as proposed.

2023 Commercial Shark Quotas

In this final rule, NMFS adjusts the quota levels for the various shark stocks and management groups for the 2023 Atlantic commercial shark fishing year (i.e., January 1 through December 31, 2023) based on underharvests that occurred during the 2022 fishing year, consistent with existing regulations at § 635.27(b). Unharvested quota may be added to the quota for the next fishing year, but only for shark management groups that have shark stocks that are declared not overfished and not experiencing overfishing. No more than 50 percent of a base annual quota may be carried over from a previous fishing year.

Based on 2022 harvests that were reported by September 30, 2022, and after considering catch rates and landings from previous years, with this final rule, NMFS adjusts the 2023 quotas for certain management groups as shown in Table 1. NMFS anticipates that dealer reports received after that time will be used to adjust 2024 quotas, as appropriate, noting that, in some circumstances, NMFS re-adjusts quotas during the subject year. A description of the calculations for each stock and management group is provided in the proposed rule and is not repeated here.

TABLE 1-2023 QUOTAS AND OPENING DATES FOR THE ATLANTIC SHARK MANAGEMENT GROUPS

Region or sub-region	Management group	2022 Annual quota	Preliminary 2022 landings ¹	Adjustments ²	2023 Base annual quota	2023 Final annual quota	Season opening date
		(A)	(B)	(C)	(D)	(D + C)	
Western Gulf of Mexico.	Blacktip Sharks	347.2 mt (765,392 lb)	220.1 mt (485,297 lb)	115.7 mt (255,131 lb)	231.5 mt (510,261 lb)	347.2 mt (765,392 lb).	January 1, 2023.
	Aggregate Large Coastal Sharks ³ .	72.0 mt (158,724 lb)	68.0 mt (149,951 lb)		72.0 mt (158,724 lb)	72.0 mt (158,724 lb).	

TABLE 1—2023 QUOTAS AND OPENING DATES FOR THE ATLANTIC SHARK MANAGEMENT GROUPS—Continued

Region or sub-region	Management group	2022 Annual quota	Preliminary 2022 landings ¹	Adjustments ²	2023 Base annual quota	2023 Final annual quota	Season opening date
		(A)	(B)	(C)	(D)	(D + C)	
	Hammerhead Sharks 4.	11.9 mt (26,301 lb)	<2.0 mt (<4,409 lb)		11.9 mt (26,301 lb)	11.9 mt (26,301 lb).	
Eastern Gulf of Mexico.	Blacktip Sharks	37.7 mt (83,158 lb)	5.2 mt (11,548 lb)	12.6 mt (27,719 lb)	25.1 mt (55,439 lb)	37.7 mt (83,158 lb).	
mexico.	Aggregate Large Coastal Sharks 3.	85.5 mt (188,593 lb)	25.5 mt (56,230 lb)		85.5 mt (188,593 lb)	85.5 mt (188,593 lb).	
	Hammerhead Sharks 4.	13.4 mt (29,421 lb)	3.6 mt (7,899 lb)		13.4 mt (29,421 lb)	13.4 mt (29,421 lb).	
Gulf of Mexico	Non-Blacknose Small Coastal Sharks.	112.6 mt (428,215 lb)	27.3 mt (60,289 lb)		112.6 mt (428,215 lb)	112.6 mt (428,215 lb).	
	Smoothhound Sharks.	504.6 mt (1,112,441 lb)	<1.0 mt (<2,205 lb)	168.2 mt (370,814 lb)	336.4 mt (741,627 lb)	504.6 mt (1,112,441 lb).	
Atlantic	Aggregate Large Coastal Sharks.	168.9 mt (372,552 lb)	61.4 mt (135,422 lb)		168.9 mt (372,552 lb)	168.9 mt (372,552 lb).	January 1, 2023.
	Hammerhead Sharks 4.	27.1 mt (59,736 lb)	23.4 mt (51,510 lb)		27.1 mt (59,736 lb)	27.1 mt (59,736 lb).	
	Non-Blacknose Small Coastal Sharks.	264.1 mt (582,333 lb)	47.5 mt (104,635 lb)		264.1 mt (582,333 lb)	264.1 mt (582,333 lb).	
	Blacknose Sharks (South of 34° N. lat. Only).	17.2 mt (3,973,902 lb)	3.5 mt (7,673 lb)		17.2 mt (3,973,902 lb)	17.2 mt (3,973,902 lb).	
	Smoothhound Sharks.	1,802.6 mt (3,973,902 lb)	267.7 mt (590,205 lb)	600.9 mt (1,324,634 lb)	1,201.7 mt (2,649,268 lb)	1,802.6 mt (3,973,902 lb).	
No Regional Quotas.	Non-Sandbar Large Coastal Shark Research.	50.0 mt (110,230 lb)	2.3 mt (4,983 lb)	,	50.0 mt (110,230 lb)	50.0 mt (110,230 lb).	January 1, 2023.
	Sandbar Shark Research.	90.7 mt (199,943 lb)	39.4 mt (86,809 lb)		90.7 mt (199,943 lb)	90.7 mt (199,943 lb).	
	Blue Sharks Porbeagle Sharks Pelagic Sharks Other Than Porbeagle or	273.0 mt (601,856 lb) 1.7 mt (3,748 lb) 488.0 mt (1,075,856 lb)	<1.0 mt (<2,205 lb) 0.0 mt (0 lb) 22.5 mt (49,622 lb)		273.0 mt (601,856 lb) 1.7 mt (3,748 lb) 488.0 mt (1,075,856 lb)	273.0 mt (601,856 lb). 1.7 mt (3,748 lb). 488.0 mt (1,075,856 lb).	

2022).

4 NMFS transferred 6.8 mt dw of the hammerhead quota from the western Gulf of Mexico sub-region to the Atlantic region on June 28, 2022 (87 FR 38676, June 29, 2022).

Opening Dates and Retention Limits

After considering the "Opening Commercial Fishing Season Criteria" listed at § 635.27(b)(3), and "Inseason Trip Limit Adjustment Criteria" listed at § 635.24(a)(8), NMFS is opening the 2023 Atlantic commercial shark fishing season for all shark management groups in the northwestern Atlantic Ocean, including the Gulf of Mexico and Caribbean Sea, on January 1, 2023 (Table 2). NMFS is also starting the 2023 commercial shark fishing season with the commercial retention limit of 55 large coastal sharks (LCS) other than sandbar sharks per vessel per trip in both the eastern and western Gulf of Mexico sub-regions as well as in the Atlantic region (Table 2). As needed, NMFS may adjust the retention limit throughout the year to ensure equitable fishing opportunities throughout the region and ensure the quota is not

exceeded (see the criteria at § 635.24(a)(8)).

All of the regional or sub-regional commercial fisheries for shark management groups would remain open until December 31, 2023, or until NMFS determines that the landings for any shark management group are projected to reach 80 percent of the quota given the realized catch rates and are projected to reach 100 percent of the quota before the end of the fishing season, or until a quota-linked species or management group is closed. For the regional or sub-regional Gulf of Mexico blacktip shark management group(s), regulations at § 635.28(b)(5)(i) through (v) authorize NMFS to close the management group(s) before landings have reached, or are projected to reach, 80 percent of the quota after considering the criteria and other relevant factors. NMFS manages each Atlantic shark

management group by using a specific commercial annual catch limit, with some linkages among shark management groups whose species are often caught together. The linked and non-linked quotas are shown in Table 2.

If NMFS determines that a shark species or management group fishery must be closed, then NMFS will publish in the Federal Register a notice of closure for that shark species, shark management group, region, and/or subregion. The closure will be effective no fewer than 4 days from the date of filing for public inspection with the Office of the Federal Register. The fisheries for the shark species or management group would be closed (even across fishing years) from the effective date and time of the closure until NMFS publishes in the Federal Register a notice that additional quota is available and the season is reopened.

TABLE 2—QUOTA LINKAGES, SEASON OPENING DATES, AND COMMERCIAL RETENTION LIMIT BY REGIONAL OR SUB-REGIONAL SHARK MANAGEMENT GROUP

Region or sub-region	Management group	Quota linkages 1	Season opening date	Commercial retention limits for directed shark limited access permit holders ²
	Blacktip SharksAggregate Large Coastal Sharks	Not LinkedLinked.	January 1, 2023	55 LCS other than sandbar sharks per vessel per trip.

Note: All quotas and landings are dressed weight (dw).

1 Landings are from January 1—September 30, 2022, and are subject to change.

2 Underharvest adjustments can only be applied to stocks or management groups that are declared not overfished and have no overfishing occurring. The underharvest adjustments cannot exceed 50 percent of the base quota.

3 NMFS transferred 11.3 mt dw of the aggregate Large Coastal Shark quota from the Gulf of Mexico eastern sub-region to the western sub-region on June 28, 2022 (87 FR 38676, June 29, 2022).

TABLE 2—QUOTA LINKAGES, SEASON OPENING DATES, AND COMMERCIAL RETENTION LIMIT BY REGIONAL OR SUB-REGIONAL SHARK MANAGEMENT GROUP—Continued

Region or sub-region			Season opening date	Commercial retention limits for directed shark limited access permit holders ²	
	Hammerhead Sharks.				
Eastern Gulf of Mexico	Blacktip Sharks Aggregate Large Coastal Sharks Hammerhead Sharks.	Not LinkedLinked.	January 1, 2023	55 LCS other than sandbar sharks per vessel per trip.	
Gulf of Mexico	Non-Blacknose Small Coastal Sharks.	Not Linked	January 1, 2023	N/A.	
	Smoothhound Sharks	Not Linked	January 1, 2023	N/A.	
Atlantic	Aggregate Large Coastal Sharks Hammerhead Sharks	Linked	January 1, 2023	55 LCS other than sandbar sharks per vessel per trip.	
	Non-Blacknose Small Coastal Sharks.	Linked (South of 34 °N lat. Only).	January 1, 2023	N/A.	
	Blacknose Sharks (South of 34 ° N lat. Only).	,,		8 blacknose sharks per vessel per trip.3	
	Smoothhound Sharks	Not Linked	January 1, 2023	N/A.	
No Regional Quotas	Non-Sandbar LCS Research Sandbar Shark Research	Linked 4	January 1, 2023	N/A.	
	Blue Sharks Porbeagle Sharks Pelagic Sharks Other Than Porbeagle or Blue.	Not Linked	January 1, 2023	N/A.	

¹ Section 635.28(b)(4) lists species and management groups with quotas that are linked. If quotas are linked, when the specified quota threshold for one management group or species is reached and that management group or species is closed, the linked management group or species closes at the same time (§ 635.28(b)(3)). ²Inseason adjustments are possible.

Response to Comments

Written comments can be found at https://www.regulations.gov/by searching "NOAA-NMFS-2022-0064." Below, NMFS summarizes and responds to the 99 written comments received on the proposed rule during the comment period. The majority of written comments were form letter submissions and are covered by Comment 1. Similar comments are combined, where appropriate.

Comment 1: NMFS received numerous comments regarding the proposed quotas and retention limits. Several commenters opposed the carryover of quota underharvests to the next fishing year because they believed that shark species must recover from a global increase in fishing pressure and that the carry-over would lead to population decline. Other commenters recommended that the base quotas and retention limits be reduced. Many of these commenters stated that quotas are not fully harvested because there are not enough sharks. Some commenters requested a prohibition on all shark fishing.

Response: The purpose of this action is to adjust the quotas and retention limits and establish the opening date for the 2023 fishing year for Atlantic shark commercial fisheries. This action does not change the regulations and management measures currently in place that govern commercial shark fishing in Federal waters of the

northwestern Atlantic Ocean, Gulf of Mexico, and Caribbean Sea.

Consistent with existing regulations at § 635.27(b), unharvested quota may be added to the quota for the next fishing year for shark management groups that have shark stocks that are declared not overfished and not experiencing overfishing. Because the Gulf of Mexico blacktip shark management group and smoothhound shark management groups in the Gulf of Mexico and Atlantic regions are not overfished, and overfishing is not occurring, available underharvest (up to 50 percent of the base annual quota) from the 2022 fishing year for these management groups may be added to their respective 2023 base quotas. NMFS previously determined that the carry-over of quota underharvests (up to 50 percent of the base annual quota) for stocks that are not overfished with no overfishing occurring would not impact the health of the stock (see Amendment 6 and Amendment 9 to the 2006 Consolidated HMS FMP (80 FR 50073, August 18, 2015; 80 FR 73128, November 24, 2015)). NMFS is not carrying forward quota underharvests for any other shark species or management group. Additionally, NMFS is not changing the base quotas or retention limits in this rule.

Furthermore, NMFS is required, under the Magnuson-Stevens Act, to foster the long-term biological and economic sustainability of shark fisheries. The majority of sharks harvested in the United States are

species with above-target population levels, and rebuilding plans are in place for all overfished species. While there are several shark species that cannot be retained, the primary objective of this final rule is to adjust the base quotas and retention limits as necessary and consistent with existing regulations at §§ 635.24(a) and 635.27(b). Prohibiting all shark fishing is contrary to that objective and to the requirements of the Magnuson-Stevens Act.

Comment 2: NMFS received a few comments regarding the data used to adjust the quotas and set the retention limits for the 2023 Atlantic shark commercial fishing year. One commenter generically challenged the accuracy of the data. Another commenter urged NMFS to continue research on shark stocks for improved data and informed management measures.

Response: NMFS uses the best scientific information available (BSIA) to effectively manage the Atlantic shark stocks (§ 600.315). In May 2022, NMFS announced the availability of the BSIA Regional Framework (see ADDRESSES). As described in the BSIA Regional Framework, NMFS may consider as BSIA the stock assessments resulting from the processes undertaken by the International Commission for the Conservation of Atlantic Tunas and the SouthEast Data Assessment and Review, as well as third-party external stock assessments that are approved for use in management by NMFS. The BSIA Regional Framework also clarifies roles

³ Applies to Shark Directed and Shark Incidental permit holders.
⁴ Shark research permits "terms and conditions" state that when the individual sandbar or research LCS quotas authorized by the permit are landed, all fishing trips under the permit must stop

and responsibilities of NMFS and collaborative bodies, and increases transparency in how BSIA determinations are made as part of the management process. All the data and stock assessments referenced in establishing the base quotas and retention limits for this rule are consistent with the BSIA Regional Framework and the Magnuson-Stevens Act

Furthermore, commercial fishermen with a shark permit must report fishing activities in an approved logbook (§ 635.5(a)(1)). Logbook entries must be species-specific and include weighout slips, among other requirements. Through improved commercial quota monitoring technology and the requirement that Atlantic HMS dealers submit weekly electronic reports on commercial-harvested Atlantic sharks, NMFS actively monitors commercial landings of all shark species and ensures that any necessary inseason management measures, such as fishery closures, occur in an efficient and timely manner. Fishermen or dealers who do not follow the regulations regarding reporting are subject to enforcement action.

Regarding research on shark stocks, NMFS uses recent research in all shark stock assessments. Additionally, NMFS works in conjunction with partners to collect scientific and biological data regarding sharks from a variety of sources, including fishery observers, fishery surveys, and the shark research fishery (§ 635.32(f)). More information on the research and data that are collected every year can be found in the annual Atlantic HMS Stock Assessment and Fishery Evaluation Report (see ADDRESSES).

Comment 3: Several commenters stated that this rulemaking is equivalent to a shark cull.

Response: The term "shark cull" refers to efforts that are made to deliberately decimate shark populations. Such efforts are contrary to NMFS' mission and the objectives of this rulemaking. NMFS is responsible for managing sustainable commercial and recreational Atlantic shark fisheries consistent with the Magnuson-Stevens Act and other applicable laws. To that end, NMFS established baseline quotas for various Atlantic shark management groups in the 2006 Consolidated HMS FMP and its amendments. These baseline quotas were established to achieve optimum yield and also to prevent overfishing and ensure rebuilding of overfished stocks (§ 600.310). NMFS adjusts these baseline quotas, as needed and as consistent with the regulations, on an

annual basis as a result of overharvest or underharvests in previous years. Because these quotas are based on BSIA, NMFS is confident that allowing commercial and recreational shark fishing in 2023 will not cause shark populations to be decimated.

Comment 4: One commenter stated that the quotas do not account for illegal shark harvest.

Response: As described in the BSIA Regional Framework, NMFS continues to use the best scientific information available to manage the shark stocks. This includes the stock assessment review process, which ensures that analyses and data used in the assessments are based on BSIA, scientifically valid and reflective of the current state of each stock or stock complex, and appropriately take into account the HMS risk policy to ensure a 70-percent likelihood of success in ending and preventing overfishing, rebuilding overfished stocks, and maintaining healthy stocks. The likelihood of success within the existing HMS risk policy considers the shark stock and relevant circumstances (e.g., data, unreported landings, fishery changes, and extenuating circumstances). Overall, the HMS risk policy is intended to ensure that the overfishing limit, allowable biological catch, and annual catch limit have buffers and are not exceeded.

NOAA's Office of Law Enforcement is responsible for investigating violations of Federal fishing regulations. Any fisherman or dealer who does not abide by the regulations is subject to potential enforcement action. As noted above, all Federal commercial shark fishermen and shark dealers are required to have permits (§ 635.4(e)), report landings (§ 635.5), and follow other requirements related to shark fishing, as specified in 50 CFR part 635. NMFS closely monitors landing reports on a weekly basis, and communicates frequently with the Office of Law Enforcement to share information about illegal shark fishing. In some instances, NMFS seizes illegally harvested shark product, pursuant to NMFS' authority under the Magnuson-Stevens Act. In those cases, the shark product is reported and counted toward the shark landings for quota monitoring purposes.

Comment 5: NMFS received numerous comments regarding concern for sharks in general. Some commenters expressed concern for what they believe are endangered and threatened shark species or incorrectly stated that endangered species in general were not considered when establishing the quotas. Other commenters noted the negative impacts of shark finning on

global shark populations. Some commenters highlighted the importance of sharks to eco-tourism, particularly for snorkeling and diving, and one commenter specifically requested stricter management measures in foreign countries to better support eco-tourism efforts. One commenter stressed the need for marine protected areas while other commenters were concerned about climate change impacts on sharks. A few commenters advocated for improved educational outreach regarding shark species and fisheries, and one commenter requested better fishing regulations. One commenter was concerned about the health risks of consuming shark meat. One commenter incorrectly stated that NMFS supports shark culls through fishing tournaments.

Response: All of these comments are beyond the scope of this rulemaking. The purpose of this action is to adjust the quotas and retention limits and establish the opening date for the 2023 fishing year for Atlantic shark commercial fisheries. This action does not change the base quotas or retention limits, which were established while considering the status of shark stocks and the requirements of the Magnuson-Stevens Act, as described in the proposed rule for this action (87 FR 55379, September 9, 2022). Information about the issues raised in these public comments can be found in the 2006 Consolidated HMS FMP and its amendments, and the annual Stock Assessment and Fishery Evaluation Report (see ADDRESSESS).

Classification

NMFS is issuing this rule pursuant to 305(d) of the Magnuson-Stevens Act. Pursuant to Magnuson-Stevens Act section 305(d), this action is necessary to carry out the 2006 Consolidated HMS FMP and its amendments in order to achieve domestic management objectives under the Magnuson-Stevens Act. The NMFS Assistant Administrator has determined that this final rule is consistent with the 2006 Consolidated HMS FMP and its amendments and other applicable law.

This action is exempt from review under Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified for the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a final regulatory flexibility analysis was not required and none was prepared.

This final rule contains no information collection requirements

under the Paperwork Reduction Act of 1995.

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

Dated: November 7, 2022.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2022–24643 Filed 11–10–22; 8:45 am]

BILLING CODE 3510-22-P

Proposed Rules

Federal Register

Vol. 87, No. 218

Monday, November 14, 2022

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.

SMALL BUSINESS ADMINISTRATION

13 CFR Parts 107 and 121

SBA Small Business Investment Company (SBIC) Proposed Regulations Webinar

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notification of webinar on

proposed regulations.

p.m. Eastern Time.

SUMMARY: The SBA is holding a webinar to update the public on proposed regulations to the Small Business Investment Company (SBIC) program contained in the proposed rule titled Small Business Investment Company Investment Diversification and Growth. **DATES:** The public webinar will be held on Monday, 11/28/2022, from 4 to 5

ADDRESSES: The Small Business Investment Company Investment Diversification and Growth Proposed Regulations Webinar will be live streamed on Microsoft Teams for the public.

FOR FURTHER INFORMATION CONTACT: The meeting will be live streamed to the public, and anyone wishing to attend or needing accommodations because of a disability can contact Nathaniel Putnam, SBA, Office of Investment & Innovation (OII), (202)714–1632, nathaniel.putnam@sba.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The U.S. Small Business
Administration ("SBA" or "Agency") is
proposing to revise the regulations for
the Small Business Investment
Company ("SBIC") program to
significantly reduce barriers to program
participation for new SBIC fund
managers and funds investing in
underserved communities and
geographies, capital intensive
investments, and technologies critical to
national security and economic
development. This proposed rule, Small
Business Investment Company

Investment Diversification and Growth, 87 FR 63436, introduces an additional type of SBIC ("Accrual SBICs") to increase program investment diversification and patient capital financing for small businesses and modernize rules to lower financial barriers to program participation. This proposed rule will help SBA implement the Executive order ("E.O."), Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, by reducing financial and administrative barriers to participate in the SBIC program and modernizing the program's license offerings to align with a more diversified set of private funds investing in underserved small businesses. The proposed rule also incorporates the statutory requirements of the Spurring Business in Communities Act of 2017, which was enacted on December 19, 2018. More information about the proposed regulation can be found here.

II. Questions

For the public webinar, OII strongly encourages that questions be submitted in advance by November 25, 2022. Individuals may email *investinnovate@sba.gov* with subject line—"[Name/Organization] Question for 11/28/22 Public Webinar." During the live event, attendees will be in listen-only mode and may submit additional questions via the Q&A Chat feature.

III. Comments on the Proposed Regulations

Comments on the proposed rule may be submitted on or before December 19th, 2022, at www.regulations.gov. SBA will analyze any written comments received and respond to all comments in the final rule. However, during the public webinar, SBA officials will not provide responses to public comment or suggestions on the proposed rule. SBA requests that commenters focus on SBA's October 19, 2022, proposed rulemaking and the impacted regulations therein. SBA requests that commenters do not raise issues pertaining to issues not covered under the proposed rule, or issues outside the scope of the rule.

IV. Information on Service for Individuals With Disabilities

For information on services for individuals with disabilities or to request special assistance contact Nathaniel Putnam at the telephone number or email address indicated under the FOR FURTHER INFORMATION CONTACT section of this notice.

Michele Schimpp,

Deputy Associate Administrator, Office of Investment & Innovation, U.S. Small Business Administration.

[FR Doc. 2022–24714 Filed 11–10–22; 8:45 am] BILLING CODE 8026–09–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2022-1296; Project Identifier MCAI-2022-00628-T]

RIN 2120-AA64

Airworthiness Directives; Airbus SAS Airplanes

Editorial Note: Proposed rule document 2022–22047 was originally published on pages 63712 through 63715 in the issue of Thursday, October 20, 2022. In that publication on page 63715, in the second column, under the "(o) Material Incorporated by Reference" heading, paragraph "(3)", "November 25, 2022" should read "[DATE 35 DAYS AFTER PUBLICATION OF THE FINAL RULE]". The corrected document is published here in its entirety.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2020-20-05 and AD 2022-09-16, which apply to certain Airbus SAS Model A318 series; A319-111, -112, -113, -114, -115, -131, -132, -133, -151N,and -153N; A320 series; and A321 series airplanes. AD 2020-20-05 and AD 2022–09–16 require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. Since the FAA issued AD 2020-20-05 and AD 2022-09-16, the FAA has determined that new or more restrictive airworthiness limitations are necessary. This proposed AD would continue to require the actions in AD 2022–09–16 and require revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive

airworthiness limitations, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. This proposed AD would also revise the applicability to include additional airplanes. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by December 5, 2022.

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

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2022–1296; 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 mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For EASA material that will be incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; internet www.easa.europa.eu. You may find this material on the EASA website at ad.easa.europa.eu.
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety 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 in the AD docket at regulations.gov under Docket No. FAA–2022–1296.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3225; email dan.rodina@faa.gov.

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 ADDRESSES. Include "Docket No. FAA-2022-1296; Project Identifier MCAI-2022-00628-T" at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to regulations.gov, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206-231-3225; email dan.rodina@faa.gov. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2020–20–05, Amendment 39–21261 (85 FR 65197, October 15, 2020) (AD 2020–20–05), and AD 2022–09–16, Amendment 39–22036

(87 FR 31943, May 26, 2022) (AD 2022-09-16), which apply to all Model A318-111, -112, -121, and -122 airplanes; Model A319-111, -112, -113, -114, -115, -131, -132, -133, -151N, and -153N airplanes; Model A320-211, -212, -214, -216, -231, -232, -233,-251N, -252N, -253N, -271N, -272N, and -273N airplanes; and Model -A321-111,-112, -131, -211, -212, -213, -231, -232, -251N, -251NX, -252N, -252NX, -253N, -253NX, -271N, -271NX, -272N, and -272NX airplanes. AD 2020-20-05 and AD 2022–09–16 require revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations. The FAA issued AD 2020-20-05 and AD 2022-09-16 to address fatigue cracking, accidental damage, or corrosion in principal structural elements, which could result in reduced structural integrity of the airplane.

Actions Since AD 2020–20–05 and AD 2022–09–16 Were Issued

Since the FAA issued AD 2020–20–05 and AD 2022–09–16, the FAA has determined that new or more restrictive airworthiness limitations are necessary.

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2022-0085, dated May 12, 2022 (EASA AD 2022-0085) (also referred to as the MCAI), to correct an unsafe condition for all Airbus SAS Model A318-111, A318-112, A318-121, A318-122, A319-111, A319–112, A319–113, A319–114, A319– 115, A319-131, A319-132, A319-133, A319-151N, A319-153N, A319-171N, A320-211, A320-212, A320-214, A320-215, A320-216, A320-231, A320-232, A320-233, A320-251N, A320-252N, A320-253N, A320-271N, A320-272N, A320-273N, A321-111, A321-112, A321-131, A321-211, A321-212, A321-213, A321-231, A321-232, A321-251N, A321-251NX, A321-252N, A321-252NX, A321-253N, A321-253NX, A321-271N, A321-271NX, A321-272N, and A321–272NX airplanes. EASA AD 2022-0085 superseded EASA AD 2020-0036R1, dated June 24, 2020 (EASA AD 2021–0140) (which corresponds to FAA AD 2020–20–05) and EASA AD 2021– 0140, dated June 14, 2021 (which corresponds to FAA AD 2022-09-16). Model A320–215 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this AD therefore does not include those airplanes in the applicability.

Airplanes with an original airworthiness certificate or original export certificate of airworthiness issued after February 2, 2022, must comply with the airworthiness limitations specified as part of the approved type design and referenced on the type certificate data sheet; this AD therefore does not include those airplanes in the applicability.

This proposed AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is proposing this AD to address fatigue cracking, accidental damage, or corrosion in principal structural elements, which could result in reduced structural integrity of the airplane. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2022–0085 specifies new or more restrictive airworthiness limitations for airplane structures and safe life limits.

This proposed AD would also require EASA AD 2021–0140, which the Director of the Federal Register approved for incorporation by reference as of June 30, 2022 (87 FR 31943, May 26, 2022).

This material 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

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI described above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of these same type designs.

Proposed AD Requirements in This NPRM

This proposed AD would retain the requirements of AD 2022–09–16. This proposed AD would also expand the applicability and require revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations, which are specified in EASA AD 2022–0085 described previously, as proposed for incorporation by reference. Any differences with EASA AD 2022–0085 are identified as exceptions in the regulatory text of this AD.

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 (AMOC) according to paragraph (m)(1) of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to retain the IBR of EASA AD 2021-0140 and incorporate EASA AD 2022-0085 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2021-0140 and EASA AD 2022-0085 in their entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2021-0140 or EASA AD 2022-0085 does not mean that operators need comply only with that section. For example, where the AD requirement refers to "all required actions and compliance times," compliance with this AD requirement is not limited to the section titled "Required Action(s) and Compliance Time(s)" in EASA AD 2021-0140 or EASA AD 2022-0085. Service information required by EASA AD 2021–0140 and EASA AD 2022–0085 for compliance will be available at regulations.gov by searching for and locating Docket No. FAA-2022-1296 after the FAA final rule is published.

Airworthiness Limitation ADs Using the New Process

The FAA's process of incorporating by reference MCAI ADs as the primary source of information for compliance with corresponding FAA ADs has been limited to certain MCAI ADs (primarily those with service bulletins as the primary source of information for accomplishing the actions required by the FAA AD). However, the FAA is now expanding the process to include MCAI ADs that require a change to airworthiness limitation documents,

such as airworthiness limitation sections.

For these ADs that incorporate by reference an MCAI AD that changes airworthiness limitations, the FAA requirements are unchanged. Operators must revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in the new airworthiness limitation document. The airworthiness limitations must be followed according to 14 CFR 91.403(c) and 91.409(e).

The previous format of the airworthiness limitation ADs included a paragraph that specified that 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 the AMOCs paragraph under "Additional FAA Provisions." This new format includes a "New Provisions for Alternative Actions and Intervals" paragraph that does not specifically refer to AMOCs, but operators may still request an AMOC to use an alternative action or interval.

Costs of Compliance

The FAA estimates that this proposed AD affects 1,864 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 2022–09–16 to be \$7,650 (90 workhours × \$85 per work-hour).

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

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

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this 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) Would not affect intrastate aviation in Alaska, and
- (3) Would 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 AD 2020–20–05, Amendment 39–21261 (85 FR 65197, October 15, 2020); and AD 2022–09–16, Amendment 39–22036 (87 FR 31943, May 26, 2022); and
- b. Adding the following new AD:

Airbus SAS: Docket No. FAA–2022–1296; Project Identifier MCAI–2022–00628–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 5, 2022.

(b) Affected ADs

This AD replaces AD 2020–20–05, Amendment 39–21261 (85 FR 65197, October 15, 2020) (AD 2020–20–05); and AD 2022– 09–16, Amendment 39–22036 (87 FR 31943, May 26, 2022) (AD 2022–09–16).

(c) Applicability

This AD applies to Airbus SAS airplanes specified in paragraphs (c)(1) through (4) of this AD, certificated in any category, with an original airworthiness certificate or original export certificate of airworthiness issued on or before February 2, 2022.

- (1) Model A318–111, –112, –121, and –122 pirplanes.
- (2) Model A319–111, –112, –113, –114, –115, –131, –132, –133, –151N, –153N, and –171N airplanes.
- (3) Model A320–211, –212, –214, –216, –231, –232, –233, –251N, –252N, –253N, –271N, –272N, and –273N airplanes.
- (4) Model A321–111, -112, -131, -211, -212, -213, -231, -232, -251N, -251NX, -252N, -252NX, -253NX, -271N, -271NX, -272N, and -272NX airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Unsafe Condition

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

(f) Compliance

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

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

This paragraph restates the requirements of paragraph (g) of AD 2022–09–16, with no changes. For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before November 10, 2020: Except as specified in paragraph (h) of this AD, comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2021–0140, dated June 14, 2021 (EASA AD 2021–0140). Accomplishing the revision of the existing maintenance or inspection program required by paragraph (j) of this AD terminates the requirements of this paragraph.

(h) Retained Exceptions to EASA AD 2021–0140

This paragraph restates the requirements of paragraph (h) of AD 2022–09–16, with no changes.

- (1) Where EASA AD 2021–0140 refers to its effective date, this AD requires using June 30, 2022 (the effective date of AD 2022–09–16).
- (2) The requirements specified in paragraphs (1) and (2) of EASA AD 2021–0140 do not apply to this AD.

- (3) Paragraph (3) of EASA AD 2021–0140 specifies revising "the approved [aircraft maintenance program] AMP" within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.
- (4) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2021–0140 is at the applicable "thresholds" as incorporated by the requirements of paragraph (3) of EASA AD 2021–0140, or within 90 days after the effective date of this AD, whichever occurs later
- (5) The provisions specified in paragraph (4) of EASA AD 2021–0140 do not apply to this AD.
- (6) The "Remarks" section of EASA AD 2021–0140 does not apply to this AD.

(i) Retained Provisions for Alternative Actions or Intervals, With No Changes

This paragraph restates the requirements of paragraph (i) of AD 2022–09–16, with no changes. After the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (e.g., inspections) or intervals are allowed unless they are approved as specified in the provisions of the "Ref. Publications" section of EASA AD 2021–0140.

(j) New Revision of the Existing Maintenance or Inspection Program

Except as specified in paragraph (k) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2022–0085, dated May 12, 2022 (EASA AD 2022–0085). Accomplishing the revision of the existing maintenance or inspection program required by this paragraph terminates the requirements of paragraph (g) of this AD.

(k) Exceptions to EASA AD 2022-0085

- (1) Where EASA AD 2022–0085 refers to its effective date, this AD requires using the effective date of this AD.
- (2) The requirements specified in paragraphs (1) and (2) of EASA AD 2022–0085 do not apply to this AD.
- (3) Paragraph (3) of EASA AD 2022–0085 specifies revising "the approved AMP" within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.
- (4) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2022–0085 is at the applicable "thresholds" as incorporated by the requirements of paragraph (3) of EASA AD 2022–0085, or within 90 days after the effective date of this AD, whichever occurs later.
- (5) The provisions specified in paragraphs (4) and (5) of EASA AD 2022–0085 do not apply to this AD.
- (6) The "Remarks" section of EASA AD 2022–0085 does not apply to this AD.

(l) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (e.g., inspections) and intervals are allowed unless they are approved as specified in the provisions of the "Ref. Publications" section of EASA AD 2022–0085.

(m) Additional FAA AD Provisions

The following provisions also apply to this AD:

- (1) Alternative Methods of Compliance (AMOCs): The Manager, Large Aircraft Section, International Validation 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 responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (n) of this AD. Information may be emailed to: 9-AVS-AIR-730-AMOC@faa.gov.
- (i) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.
- (ii) AMOCs approved previously for AD 2022–09–16 are approved as AMOCs for the corresponding provisions of EASA AD 2021–0140 that are required by paragraph (g) of this AD
- (2) Contacting the Manufacturer: For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(n) Related Information

For more information about this AD, contact Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3225; email dan.rodina@faa.gov.

(o) 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.
- (3) The following service information was approved for IBR on [DATE 35 DAYS AFTER PUBLICATION OF THE FINAL RULE].
- (i) European Union Aviation Safety Agency (EASA) AD 2022–0085, dated May 12, 2022.
 - (ii) [Reserved]
- (4) The following service information was approved for IBR on June 30, 2022 (87 FR 31943, May 26, 2022).
- (i) European Union Aviation Safety Agency (EASA) AD 2021–0140, dated June 14, 2021.

- (ii) [Reserved]
- (5) For the EASA ADs identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; website easa.europa.eu. You may find these EASA ADs on the EASA website at ad.easa.europa.eu.
- (6) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.
- (7) 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 fr.inspection@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibrlocations.html.

Issued on October 3, 2022.

Christina Underwood,

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

[FR Doc. R1–2022–22047 Filed 11–10–22; 8:45 am] **BILLING CODE 0099–10–P**

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2022-1240; Project Identifier AD-2022-00683-E]

RIN 2120-AA64

Airworthiness Directives; General Electric Company Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain General Electric Company (GE) GE90-76B, GE90-85B, GE90-90B, and GE90–94B model turbofan engines. This proposed AD was prompted by a commanded in-flight shutdown (IFSD) due to cracking and rockback of the high-pressure turbine (HPT) stage 2 nozzles resulting in blade liberation, severe rotor imbalance, and liberation of the exhaust centerbody. This proposed AD would require initial and repetitive borescope inspections (BSIs) of the forward platforms of the HPT stage 2 blades or the leading edges of the HPT stage 2 nozzles and, depending on the results of the inspections, removal and replacement of the HPT stage 2 nozzles with a part eligible for installation. As a mandatory terminating action to the repetitive BSIs of the forward platforms of the HPT stage 2 blades or the leading

edges of the HPT stage 2 nozzles, this proposed AD would require replacement of the HPT stage 2 nozzles. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by December 29, 2022.

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 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.

AD Docket: You may examine the AD docket at regulations.gov by searching for and locating Docket No. FAA–2022–1240; 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, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference: For service information identified in this NPRM, contact General Electric Company, GE Aviation, Room 285, 1 Neumann Way, Cincinnati, OH 45215; phone: (513) 552–3272; email: aviation.fleetsupport@ge.com. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

FOR FURTHER INFORMATION CONTACT:

Stephen Elwin, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7236; email: Stephen.L.Elwin@faa.gov.

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 ADDRESSES. Include "Docket No. FAA-2022-1240; Project Identifier AD-2022-00683-E" at the beginning of your comments. The most helpful comments reference a specific portion of the

proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to regulations.gov, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Stephen Elwin, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA received a report of a commanded IFSD of a GE90–85B model turbofan engine installed on a Boeing

Model 777-200ER airplane that occurred on July 12, 2018, Subsequent investigation by the manufacturer found that cracking and rockback of the HPT stage 2 nozzles, due to thermal distress in the fillet radius of the leading edge, resulted in rotor-stator contact with the HPT stage 2 blade platform. This condition caused liberation of an HPT stage 2 blade and severe rotor imbalance, leading to liberation of the exhaust centerbody from the engine. This condition, if not addressed, could result in IFSD, failure of the engine and exhaust centerbody, and loss of the airplane.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed GE GE90 Service Bulletin (SB) 72–1166, Revision 3, dated February 14, 2019. This service information specifies procedures for BSIs of the HPT stage 2 blade forward platforms for rub marks or evidence of contact (circumferential grooves on the HPT stage 2 blade platforms) with the HPT stage 2 nozzle angel wings. This service information also specifies procedures for performing a 360-degree BSI of the HPT stage 2 nozzles leading edges and specifies procedures for removal and replacement of HPT stage 2 nozzles.

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 **ADDRESSES**.

Other Related Service Information

The FAA reviewed GE GE90 SB 72–1071, Revision 1, dated January 16, 2015. This service information specifies

procedures for removal and replacement of HPT stage 2 nozzles with HPT stage 2 nozzles that incorporate a design change.

The FAA also reviewed GE GE90 SB 72–1216, Initial Issue, dated August 22, 2022. This service information specifies inspection procedures for affected HPT stage 2 nozzles.

Proposed AD Requirements in This NPRM

This proposed AD would require initial and repetitive borescope inspections of the forward platforms of the HPT stage 2 blades or the leading edges of the HPT stage 2 nozzles and, depending on the results of the inspections, removal and replacement of the HPT stage 2 nozzles with parts eligible for installation. As a mandatory terminating action to the repetitive BSIs of the forward platforms of the HPT stage 2 blades or the leading edges of the HPT stage 2 nozzles, this proposed AD would require replacement of the HPT stage 2 nozzles.

Differences Between This Proposed AD and the Service Information

GE GE90 SB 72–1166, Revision 3, dated February 14, 2019, specifies BSIs be performed upon reaching the threshold of the analytical model for the HPT stage 2 nozzles after GE Aviation issues a customer notification report for any engine that reaches the analytical threshold, while this proposed AD would require that BSIs be performed based on the flight hours accrued on the HPT stage 2 nozzles since new or since overhaul.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 8 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
BSI of HPT stage 2 nozzles or HPT stage 2 blade interface.	4 work-hours × \$85 per hour = \$340	\$0	\$340	\$2,720

The FAA estimates the following costs to do any necessary replacements that would be required based on the

results of the proposed inspections. The agency has no way of determining the

number of aircraft that might need these replacements.

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace full set of HPT stage 2 nozzles	8 work-hours × \$85 per hour = \$680	\$918,650	\$919,330

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this 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) Would not affect intrastate aviation in Alaska, and
- (3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

General Electric Company: Docket No. FAA– 2022–1240; Project Identifier AD–2022– 00683–E.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 29, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to General Electric Company (GE) GE90–76B, GE90–85B, GE90–90B, and GE90–94B model turbofan engines, excluding those engines with an installed full set of high-pressure turbine (HPT) stage 2 nozzles with part numbers 1847M47G23 and 1847M47G24.

(d) Subject

Joint Aircraft System Component (JASC) Code 7250, Turbine Section.

(e) Unsafe Condition

This AD was prompted by a commanded in-flight shutdown (IFSD) due to cracking and rockback of the HPT stage 2 nozzles resulting in blade liberation, severe rotor imbalance, and liberation of the exhaust centerbody. The FAA is issuing this AD to prevent failure of the HPT stage 2 nozzles, HPT stage 2 blades, and exhaust centerbody. The unsafe condition, if not addressed, could result in IFSD, failure of the engine and exhaust centerbody, and loss of the airplane.

(f) Compliance

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

(g) Required Actions

- (1) Within the compliance times specified in paragraphs (g)(1)(i) and (ii) of this AD, perform an initial borescope inspection (BSI) of the forward platforms of the HPT stage 2 blades, or perform a 360 degree BSI of the leading edges of the HPT stage 2 nozzles (optional procedure) in accordance with the Accomplishment Instructions, paragraph 3.A.(3)(a) of GE GE90 SB 72–1166, Revision 3, dated February 14, 2019 (the SB):
- (i) For engines with HPT stage 2 nozzles that have accumulated 22,000 or more flight

hours since new or since last overhaul as of the effective date of this AD, perform the initial BSI before accumulating 250 flight cycles (FCs) after the effective date of this AD.

- (ii) For engines with HPT stage 2 nozzles that have accumulated less than 22,000 flight hours since new or since last overhaul as of the effective date of this AD, perform the initial BSI before accumulating 22,000 flight hours since new or since last overhaul, or within 250 FCs after the effective date of this AD, whichever occurs later.
- (2) Thereafter, at intervals not to exceed 100 FCs from performance of the last BSI of the forward platforms of the HPT stage 2 blades, or at intervals not to exceed 500 FCs from the last BSI of the leading edges of the HPT stage 2 nozzles, as applicable, perform a repetitive BSI of the forward platforms of the HPT stage 2 blades or the leading edges of the HPT stage 2 nozzles in accordance with the Accomplishment Instructions, paragraph 3.A.(3)(a) of the SB.

(3) If, during any inspection required by paragraphs (g)(1) or (g)(2) of this AD, rub marks, evidence of contact on the HPT stage 2 blade forward platform on three or more HPT stage 2 blades, or an unserviceable HPT stage 2 nozzle is found, before further flight, remove and replace the HPT stage 2 nozzles with a part eligible for installation.

Note 1 to paragraph (g)(3): Serviceability criteria can be found in the GE90 Boeing 777 Aircraft Maintenance Manual, 72–00–00, INSPECTION/CHECK, Subtask 72–00–00–220–074–G00.

(h) Mandatory Terminating Action

As a mandatory terminating action to the repetitive inspections required by paragraph (g)(2) of this AD, at the next engine shop visit after reaching 22,000 flight hours since new or since last overhaul, replace the HPT stage 2 nozzles with parts eligible for installation.

(i) Definitions

- (1) For the purpose of this AD, "parts eligible for installation" is a full set of HPT stage 2 nozzles with part numbers 1847M47G23 and 1847M47G24.
- (2) For the purpose of this AD, an "overhaul" is the complete refurbishment of the HPT stage 2 nozzle segments.
- (3) For the purpose of this AD, and "engine shop visit" is the induction of an engine into the shop for maintenance involving separation of pairs of major mating engine case flanges, except for the following situations, which do not constitute an engine shop visit:
- (i) Separation of engine flanges solely for the purposes of transportation of the engine without subsequent maintenance; or
- (ii) Separation of engine flanges solely for the purpose of replacing the fan or propulsor without subsequent maintenance.

(j) Credit for Previous Actions

You may take credit for the initial inspection required by paragraph (g)(1) of this AD if you performed the inspection before the effective date of this AD using GE GE90 SB 72–1166, Revision 2, dated October 13, 2017, or earlier revisions.

(k) Alternative Methods of Compliance (AMOCs)

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

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

(l) Related Information

(1) For more information about this AD, contact Stephen Elwin, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7236; email: Stephen.L.Elwin@faa.gov.

(2) GE service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraph (m)(3) of this AD.

(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 the AD specifies otherwise.

(i) GE GE90 Service Bulletin (SB) 72–1166, Revision 3, dated February 14, 2019.

(ii) [Reserved]

(3) For GE service information identified in this AD, contact General Electric Company, GE Aviation, Room 285, 1 Neumann Way, Cincinnati, OH 45215; phone: (513) 552–3272; email: aviation.fleetsupport@ge.com.

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA, 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

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

Issued on September 26, 2022.

Christina Underwood,

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

[FR Doc. 2022–23911 Filed 11–10–22; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2022-0546; Airspace Docket No. 22-ASW-10]

RIN 2120-AA66

Proposed Amendment of Class D and Class E Airspace; Rogers, Springdale, and Bentonville, AR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking

(NPRM).

SUMMARY: This action proposes to amend Class D airspace and Class E surface airspace for the following Arkansas airports: Rogers Executive Airport-Carter Field (new name), Springdale Municipal Airport, and Bentonville Municipal Airport/Louise M Thaden Field (new name), as well as updating the airport's names and geographic coordinates. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

DATES: Comments must be received on or before December 29, 2022.

ADDRESSES: Send comments on this proposal to: the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; Telephone: (800) 647–5527, or (202) 366–9826. You must identify Docket No. FAA–2022–0546; Airspace Docket No. 22–ASW–10 at the beginning of your comments. You may also submit comments through the internet at www.regulations.gov.

FAA Order JO 7400.11G Airspace Designations and Reporting Points and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. For further information, contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone: (404) 305–6364.

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 airspace in Rogers, Springdale, and Bentonville, AR, to support IFR operations in the area.

Comments Invited

Interested persons are invited to comment on 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 (Docket No. FAA–2022–0546 and Airspace Docket No. 22–ASW–10) and be submitted in triplicate to DOT Docket Operations (see ADDRESSES section for the address and phone number). You may also submit comments through the internet at

www.regulations.gov.
Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA-2022-0546; Airspace Docket No. 22-ASW-10." The postcard will be dated/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 in this document may be changed in light of the comments received. All comments submitted will be available for examination in the public docket before and after the comment closing date. 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 www.regulations.gov. Recently published rulemaking documents can also be accessed through the FAA's web page at 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 address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except on federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except for federal holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350,1701 Columbia Avenue, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to 14 CFR part 71 to amend Class D airspace for Rogers Executive Airport-Carter Field (formerly Rogers Municipal/Carter Field) and Springdale Municipal Airport by updating each airport's geographic coordinates to coincide with the FAA's database. Also, Class E surface airspace would be amended for the above airports and Bentonville Municipal Airport/Louise M Thaden Field (formerly Bentonville Municipal/Louise M. Thadden Field). This action would also update the airport's names and the dividing line of the Class D airspace between Rogers Executive Airport-Carter Field with the Class E surface airspace of Bentonville Municipal Airport/Louise M Thaden Field. In addition, this action would replace the outdated terms Airport/ Facility Directory with the term Chart Supplement and Notice to Airmen with the term Notice to Air Missions in the airspace descriptions.

Class D and E airspace designations are published in Paragraphs 5000 and 6002, respectively, of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace

designations listed in this document will subsequently be published in FAA Order JO 7400.11.

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

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will 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.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, 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 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 Federal Aviation Administration Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 5000 Class D Airspace.

ASW AR D Rogers, AR [Amended]

Rogers Executive Airport-Carter Field, AR (Lat. 36°22′21″ N, long. 94°06′25″ W) Razorback VOR

(Lat. 36°14'47" N, long. 94°07'17" W)

That airspace extends upward from the surface up to but not including 3,900 feet MSL within a 4-mile radius of Rogers Executive Airport-Carter Field and within 2.2 miles each side of the 005 ° radial of the Razorback VOR extending from the 4-miles radius to 6.0 miles south of the airport excluding that airspace west of a line (Lat. 36°24′09" N, long. 94°10′51" W and lat. 36°18′53" N, long. 94°08′55" W), and excluding the Class C airspace associated with the Northwest Arkansas Regional airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will, after that, be continuously published in the Chart Supplement.

ASW AR D Springdale, AR [Amended]

Springdale Municipal Airport, AR (Lat. 36°10′35″ N, long. 94°07′09″ W) Razorback VOR

(Lat. 36°14'47" N, long. 94°07'17" W)

That airspace extending upward from the surface to and including 3,900 feet MSL within a 4.1-mile radius of Springdale Municipal Airport and within 1.3 miles each side of the 358° and 178° radials of the Razorback VORTAC extending from the 4.1-mile radius to 4.6 miles north of the airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will, after that, be continuously published in the Chart Supplement.

Paragraph 6002 Class E Surface Airspace.

ASW AR E2 Rogers, AR [Amended]

Rogers Executive Airport-Carter Field, AR (Lat. 36°22′21″ N, long. 94°06′25″ W) Razorback VOR

(Lat. 36°14′47″ N, long. 94°07′17″ W)

That airspace extends upwards from the surface within a 4-mile radius of Rogers Executive Airport-Carter Field and within 2.2 miles on each side of the 005° radial of the Razorback VOR, extending from the 4-miles radius to 6.0 miles south of the airport, excluding that airspace west of a line (Lat. 36°24′09″ N, long. 94°10′51″ W, and lat. 36°18′53″ N, long. 94°08′55″ W). This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will, after that, be continuously published in the Chart Supplement.

ASW AR E2 Springdale, AR [Amended]

Springdale Municipal Airport, AR (Lat. 36°10′35″ N, long. 94°07′09″ W) Razorback VORTAC

(Lat. 36°14'47" N, long. 94°07'17" W)

That airspace extends upwards from the surface within a 4.1-mile radius of

Springdale Municipal Airport and 1.3 miles on each side of the 358° and 178° radials of the Razorback VORTAC extending from the 4.1-mile radius to 4.6 miles north of the airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will, after that, be continuously published in the Chart Supplement.

ASW AR E2 Bentonville, AR [Amended]

Bentonville Municipal/Louise M. Thaden Field, AR

(Lat. 36°20′43″ N, long. 94°13′10″ W) Razorback VOR

(Lat. 36°14′47" N, long. 94°07′17" W)

That airspace extends upwards from the surface within a 3.9-mile radius of Bentonville Municipal Airport and within 2.2 miles on each side of the 322° radial of the Razorback VOR, extending from the 3.9-mile radius to 6 miles southeast of the airport, excluding that airspace east of a line (Lat. 36°24′09″ N, long. 94°10′51″ W, and lat. 36°18′53″ N, long. 94°08′55″ W). This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

Issued in College Park, Georgia, on November 7, 2022.

Lisa Burrows,

Manager, Airspace & Procedures Team North, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2022–24599 Filed 11–10–22; $8:45~\mathrm{am}$]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 50, 56, and 812

[Docket Nos. FDA-2021-N-0286 and FDA-2019-N-2175]

RIN 0910-AI07 and 0910-AI08

Protection of Human Subjects and Institutional Review Boards, and Institutional Review Boards; Cooperative Research; Extension of Comment Period

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed rules; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for two proposed rules that appeared in the Federal Register of September 28, 2022. In the proposed rule entitled "Protection of Human Subjects and Institutional Review Boards," FDA

requested comments on proposed changes to its regulations regarding obtaining and documenting informed consent from research participants, and institutional review board membership and functions, including continuing review (Docket No. FDA-2021-N-0286). In the proposed rule entitled "Institutional Review Boards; Cooperative Research," FDA requested comment on a change to its regulations that would require any institution located in the United States participating in FDA-regulated cooperative research to rely on approval by a single institutional review board (IRB) for that portion of the research that is conducted in the United States, with some exceptions (Docket No. FDA-2019-N-2175). The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the proposed rules published in the **Federal Register** on September 28, 2022 (87 FR 58733 and 87 FR 58752). Either electronic or written comments must be submitted by December 28, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 28, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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-2021-N-0286 for "Protection of Human Subjects and Institutional Review Boards" and/or Docket No. FDA-2019-N-2175 for "Institutional Review Boards; Cooperative Research." 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, 240-402-7500.

 Čonfidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For

more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

With regard to Docket No. FDA–2021–N–0286: Sheila Brown, Office of Clinical Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–6563. With regard to Docket No. FDA–2019–N–2175: David Markert, Office of Clinical Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–0752.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 28, 2022, FDA published two proposed rules with a 60-day comment period to request comments on proposed changes to its regulations regarding obtaining and documenting informed consent from research participants, and institutional review board membership and functions, including continuing review, as well as a change to its regulations that would require any institution located in the United States participating in FDA-regulated cooperative research to rely on approval by a single IRB for that portion of the research that is conducted in the United States, with some exceptions. Comments on the proposed rules will inform FDA's rulemaking to establish regulations for Protection of Human Subjects and Institutional Review Boards.

The Agency has received requests for a 60-day extension of the comment period for both proposed rules. The requests conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rules.

FDA has considered the requests and is extending the comment periods for the proposed rules for 30 days. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

Dated: November 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy. [FR Doc. 2022–24689 Filed 11–10–22; 8:45 am] BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51 and 52

[EPA-HQ-OAR-2004-0014; FRL-4940.2-04-OAR]

Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR): Reconsideration of Fugitive Emissions Rule; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: On October 14, 2022, the Environmental Protection Agency (EPA) proposed a rule titled, "Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR): Reconsideration of Fugitive Emissions Rule," FR Doc 2022–22259. The EPA has received a request for additional time to review and comment on the proposed rule revisions. The EPA is extending the comment period on the proposed rule that was scheduled to close on December 13, 2022, for sixty days.

DATES: The public comment period for the proposed rule published in the **Federal Register** on October 14, 2022 (87 FR 62322), is being extended for sixty days. Written comments must be received on or before February 14, 2023.

ADDRESSES: The EPA has established docket number EPA–HQ–OAR–2004–

0014 for this action. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e., on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions and general guidance on making effective comments, please visit http://www2.epa.gov/dockets/ commenting-epa-dockets.

FOR FURTHER INFORMATION CONTACT: For additional information on this action, contact Mr. Ben Garwood, Air Quality Policy Division, Office of Air Quality Planning and Standards (C539–01), Environmental Protection Agency, 109 TW Alexander Drive, Research Triangle Park, NC 27711; telephone number: (919)–541–1358; email address: Garwood.ben@epa.gov.

SUPPLEMENTARY INFORMATION: After considering the requests to extend the public comment period received from various parties, the EPA has decided to extend the public comment period until February 14, 2023. This extension will ensure that the public has additional time to review the proposed rule. At the party's request, the EPA will add a redline/strikeout of the rule text to the docket. This will provide specificity and clarity to the proposed rule text changes.

Scott Mathias,

Director, Air Quality Policy Division, Office of Air Quality Planning and Standards.
[FR Doc. 2022–24662 Filed 11–10–22; 8:45 am]
BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 87, No. 218

Monday, November 14, 2022

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

Forest Service

Boundary Establishment for South Fork Roaring River National Wild and Scenic River, Mt. Hood National Forest, Clackamas County, Oregon

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of availability.

SUMMARY: In accordance with the Wild and Scenic Rivers Act, the USDA Forest Service, Washington Office, is transmitting the final boundary of South Fork Roaring River National Wild and Scenic River to Congress. The South Fork Roaring River Wild and Scenic River boundary description is available for review on https://www.fs.usda.gov/main/mthood/landmanagement/planning.

ADDRESSES: The South Fork Roaring River National Wild and Scenic River boundary is available for review at the website listed under SUMMARY, to view the documents in person, arrangements should be made in advance by contacting the offices listed under SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT:

Information may be obtained by contacting John Matthews, Regional Land Surveyor, by telephone at 503–808–2420 or via email at *john.matthews@usda.gov.* Alternatively, contact Michelle Lombardo on the Mt. Hood National Forest at 971–303–2083 or *michelle.lombardo@usda.gov.* Individuals who use

Telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339 between 8 a.m. and 8 p.m., eastern standard time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The South Fork Roaring River Wild and Scenic River boundary is available for review

on the website listed under **SUMMARY**, or in person by contacting the following Offices: USDA Forest Service, Yates Building, 14th and Independence Avenues SW, Washington, DC 20024, phone—800–832–1355; Pacific Northwest Regional Office, 1220 SW Third Avenue, Portland, OR 97204, phone—503–808–2468; and Mt Hood National Forest Supervisor's Office, 16400 Champion Way, Sandy, OR 97055, phone—503–668–1700. Please contact the appropriate office prior to arrival.

Persons with disabilities who require alternative means of communication for program information (e.g., Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at 202–720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at 800–877–8339. Additionally, program information may be made available in languages other than English.

The Omnibus Public Land
Management Act of 2009 (Pub. L. 111–
11) of March 30, 2009, designated South
Fork Roaring River, Oregon as a
National Wild and Scenic River, to be
administered by the Secretary of
Agriculture. As specified by law, the
boundary will not be effective until
ninety days after Congress receives the
transmittal.

Dated: November 7, 2022.

Jacqueline Emanuel,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2022–24628 Filed 11–10–22; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE

Forest Service

Comprehensive River Management Plan for the Red Wild and Scenic River on Daniel Boone National Forest, Forest Service, Menifee, Wolfe and Powell Counties, Kentucky

AGENCY: Forest Service, USDA. **ACTION:** Notice of availability.

SUMMARY: In accordance with Section 3(d)(1) of the Wild and Scenic Rivers Act, the USDA Forest Service announces the completion and

availability of a comprehensive river management plan (CRMP) for the Red Wild and Scenic River. A 19.4 mile segment of the Red River was designated by Congress in the Red River Designation Act of 1993, as a national wild and scenic river and managed by the Forest Service.

FOR FURTHER INFORMATION CONTACT:

Information may be obtained by contacting Jonathan Kazmierski, Cumberland District Ranger, 2375 KY 801 South, Morehead, KY 40351, 606–784–6428, ext. 100, or at jon.kazmierski@usda.gov.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: On

September 7, 2022, the Daniel Boone National Forest Forest signed a decision notice to adopt the CRMP for Red Wild and Scenic River on National Forest System Lands. The CRMP addresses resource protection, development of lands and facilities, user capacities, and other management practices necessary or desirable to achieve the purposes of the Wild and Scenic Rivers Act. This CRMP was prepared after consultation with Tribes, State and local governments, and interested public. An environmental assessment (EA) was prepared as part of the CRMP development, in compliance with the National Environmental Policy Act and other relevant federal laws and regulations. The EA discloses the direct, indirect, and cumulative environmental effects that would result from adopting the CRMP. The CRMP, EA and decision notice are available for review at: https://www.fs.usda.gov/project/ ?project=59892. Also, the documents are available at the Daniel Boone National Forest Supervisor's Office, 1700 Bypass Road, Winchester, KY 40391.

Dated: November 7, 2022.

Jacqueline Emanuel,

Acting Associate Deputy Chief, Nationial Forest System.

[FR Doc. 2022–24624 Filed 11–10–22; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE

Forest Service

Boundary Establishment for Salmon National Wild and Scenic River, Mt. Hood National Forest and Bureau of Land Management, Salem District, Clackamas, Hood River, and Wasco Counties, Oregon

AGENCY: Forest Service, Agriculture (USDA) and Bureau of Land Management, Department of Interior (USDOI).

ACTION: Notice of availability.

SUMMARY: In accordance with Section 3(b) of the Wild and Scenic Rivers Act, the USDA Forest Service, Washington Office, is transmitting the final boundary of Salmon National Wild and Scenic River to Congress. The Salmon Wild and Scenic River boundary description is available for review on https://www.fs.usda.gov/main/mthood/landmanagement/planning.

ADDRESSES: The Salmon Wild and Scenic River boundary is available for review at the website listed under SUMMARY, to view the documents in person, arrangements should be made in advance by contacting the offices listed under SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT:

Information may be obtained by contacting John Matthews, Forest Service Regional Land Surveyor, by telephone at 503–808–2420 or via email at *john.matthews@usda.gov*.

Alternatively, contact Michelle Lombardo on the Mt. Hood National Forest at 971–303–2083 or *michelle.lombardo@usda.gov*; or, Bureau of Land Management Oregon State Office, 1220 SW 3rd Ave., Portland, OR 97204; 503–808–6001.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Salmon Wild and Scenic River boundary is available for review on the website listed under SUMMARY, or in person at the following offices: USDA Forest Service, Yates Building, 14th and Independence Avenues SW, Washington, DC 20024, phone—800—832—1355; Pacific Northwest Regional Office, 1220 SW Third Avenue, Portland, OR 97204, phone—503—808—2468; and Mt Hood National Forest Supervisor's Office, 16400 Champion Way, Sandy, OR 97055; USDOI, Bureau

of Land Management National Office, (DOI Library), 1849 C St. NW, Washington, DC 20240, Bureau of Land Management Oregon State Office, 1220 SW 3rd Ave., Portland, OR 97204; 503–808–6001. Please contact the appropriate office prior to arrival.

Persons with disabilities who require alternative means of communication for program information (e.g., Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at 202–720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at 800–877–8339. Additionally, program information may be made available in languages other than English.

Public Law 100–557 of October 28, 1988, designated Salmon, Oregon as a National Wild and Scenic River, to be administered by the Secretary of Agriculture and the Secretary of Interior. As specified by law, the boundary will not be effective until ninety days after Congress receives the transmittal.

Dated: November 7, 2022.

Jacqueline Emanuel,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2022-24627 Filed 11-10-22; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE

Forest Service

Boundary Establishment for Fifteenmile Creek National Wild and Scenic River, Mt. Hood National Forest, Hood River and Wasco Counties, Oregon

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of availability.

SUMMARY: In accordance with Section 3(b) of the Wild and Scenic Rivers Act, the USDA Forest Service, Washington Office, is transmitting the final boundary of Fifteenmile Creek National Wild and Scenic River to Congress. The Fifteenmile Creek Wild and Scenic River boundary description is available for review on https://www.fs.usda.gov/main/mthood/landmanagement/planning.

ADDRESSES: The Fifteenmile Wild and Scenic River boundary is available for review at the website listed under SUMMARY, to view the documents in person, arrangements should be made in

advance by contacting the offices listed under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT:

Information may be obtained by contacting John Matthews, Regional Land Surveyor, by telephone at 503–808–2420 or via email at john.matthews@usda.gov. Alternatively, contact Michelle Lombardo on the Mt. Hood National Forest at 971–303–2083 or michelle.lombardo@usda.gov. Individuals who use Telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Fifteenmile Creek Wild and Scenic River boundary is available for review on the website listed under SUMMARY, or in person by contacting the following offices: USDA Forest Service, Yates Building, 14th and Independence Avenues SW, Washington, DC 20024, phone-800-832-1355; Pacific Northwest Regional Office, 1220 SW Third Avenue, Portland, OR 97204, phone-503-808-2468; and Mt Hood National Forest Supervisor's Office, 16400 Champion Way, Sandy, OR 97055, phone—503–668–1700. Please contact the appropriate office prior to arrival.

Persons with disabilities who require alternative means of communication for program information (e.g., Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at 202–720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at 800–877–8339. Additionally, program information may be made available in languages other than English.

The Omnibus Public Land
Management Act of 2009 (Pub. L. 111–
11) of March 30, 2009, designated
Fifteenmile Creek, Oregon as a National
Wild and Scenic River, to be
administered by the Secretary of
Agriculture. As specified by law, the
boundary will not be effective until
ninety days after Congress receives the
transmittal.

Dated: November 7, 2022.

Jacqueline Emanuel,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2022-24625 Filed 11-10-22; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE

Forest Service

Boundary Establishment for Middle Fork Hood River National Wild and Scenic River, Mt. Hood National Forest, Hood River County, Oregon

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of availability.

SUMMARY: In accordance with Section 3(b) of the Wild and Scenic Rivers Act, the USDA Forest Service, Washington Office, is transmitting the final boundary of Middle Fork Hood River National Wild and Scenic River to Congress. The Middle Fork Hood River Wild and Scenic River boundary description is available for review on https://www.fs.usda.gov/main/mthood/landmanagement/planning.

ADDRESSES: The Middle Fork Hood River Wild and Scenic River boundary is available for review at the website listed under SUMMARY, to view the documents in person, arrangements should be made in advance by contacting the offices listed under SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT:

Information may be obtained by contacting John Matthews, Regional Land Surveyor, by telephone at 503–808–2420 or via email at *john.matthews@usda.gov.* Alternatively, contact Michelle Lombardo on the Mt. Hood National Forest at 971-303–2083 or *michelle.lombardo@usda.gov.* Individuals who use Telecommunication devices for the deaf

Telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Middle Fork Hood River Wild and Scenic River boundary description is available for review on the website listed under **SUMMARY**, or in person by contacting the following offices: USDA Forest Service, Yates Building, 14th and Independence Avenues SW, Washington, DC 20024, phone—800– 832-1355; Pacific Northwest Regional Office, 1220 SW Third Avenue, Portland, OR 97204, phone—503-808-2468; and Mt Hood National Forest Supervisor's Office, 16400 Champion Way, Sandy, OR 97055, phone—503-668-1700. Please contact the appropriate office prior to arrival.

Persons with disabilities who require alternative means of communication for program information (e.g., Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at 202–720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at 800–877–8339. Additionally, program information may be made available in languages other than English.

The Omnibus Public Land
Management Act of 2009 (Pub. L. 111–
11) of March 30, 2009, designated
Middle Fork Hood River, Oregon as a
National Wild and Scenic River, to be
administered by the Secretary of
Agriculture. As specified by law, the
boundary will not be effective until
ninety days after Congress receives the
transmittal.

Dated: November 7, 2022.

Jacqueline Emanuel,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2022–24626 Filed 11–10–22; 8:45 am] BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Boundary Establishment for Collawash National Wild and Scenic River, Mt. Hood National Forest, Clackamas and Marion Counties, Oregon

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of availability.

SUMMARY: In accordance with Section 3(b) of the Wild and Scenic Rivers Act, the USDA Forest Service, Washington Office, is transmitting the final boundary of Collawash National Wild and Scenic River to Congress. The Collawash Wild and Scenic River boundary description is available for review at the following website: https://www.fs.usda.gov/main/mthood/landmanagement/planning.

ADDRESSES: The Collawash Wild and Scenic River boundary is available for review at the website listed under SUMMARY, to view the documents in person, arrangements should be made in advance by contacting the offices listed under SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT:

Information may be obtained by contacting John Matthews, Regional Land Surveyor, by telephone at (503) 808–2420 or via email at *john.matthews@usda.gov*. Alternatively, contact Michelle Lombardo on the Mt. Hood National Forest at (971) 303–2083 or *michelle.lombardo@usda.gov*. Individuals who use Telecommunication devices for the deaf

Telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339

between 8 a.m. and 8 p.m., eastern standard time, Monday through Friday. **SUPPLEMENTARY INFORMATION:** The Collawash Wild and Scenic River boundary description is available for review on the website listed under SUMMARY, or in person by contacting the following offices: USDA Forest Service, Yates Building, 14th and Independence Avenues SW, Washington, DC 20024, phone-800-832-1355; Pacific Northwest Regional Office, 1220 SW Third Avenue, Portland, OR 97204, phone-503-808-2468; and Mt Hood National Forest Supervisor's Office, 16400 Champion Way, Sandy, OR 97055, phone—503-668-1700. Please contact the appropriate office prior to

Persons with disabilities who require alternative means of communication for program information (e.g., Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at 202–720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at 800–877–8339. Additionally, program information may be made available in languages other than English.

The Omnibus Public Land Management Act of 2009 (Pub. L. 111– 11) of March 30, 2009, designated Collawash, Oregon as a National Wild and Scenic River, to be administered by the Secretary of Agriculture. As specified by law, the boundary will not be effective until ninety days after Congress receives the transmittal.

Dated: November 7, 2022.

Jacqueline Emanuel,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2022–24633 Filed 11–10–22; 8:45 am] BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-49-2022]

Foreign-Trade Zone 28—New Bedford, Massachusetts; Application for Reorganization Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the City of New Bedford, grantee of FTZ 28, requesting authority to reorganize the zone under the alternative site framework (ASF) adopted by the FTZ Board (15 CFR Sec. 400.2(c)). The ASF is an option for grantees for the establishment or reorganization of zones and can permit significantly greater flexibility in the designation of new subzones or "usage-driven" FTZ sites for operators/users located within a grantee's "service area" in the context of the FTZ Board's standard 2,000-acre activation limit for a zone. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on November 7, 2022.

FTZ 28 was approved by the FTZ Board on April 5, 1977 (Board Order 117, 42 FR 18901, April 11, 1977).

The current zone includes the following sites: Site 1 (13.5 acres)—New Bedford Regional Airport, Aviation Way, New Bedford, Bristol County; and, Site 2 (9 acres)—New Bedford Industrial Park, John Vertente Blvd., New Bedford, Bristol County.

The grantee's proposed service area under the ASF would be Bristol, Barnstable, Dukes, Nantucket, Norfolk and Plymouth Counties, Massachusetts, as described in the application. If approved, the grantee would be able to serve sites throughout the service area based on companies' needs for FTZ designation. The application indicates that the proposed service area is within and adjacent to the New Bedford, Massachusetts Customs and Border Protection port of entry.

The applicant is requesting authority to reorganize its existing zone to include both existing sites as "magnet" sites. No subzones/usage-driven sites are being requested at this time. The application would have no impact on FTZ 28's previously authorized subzones.

In accordance with the FTZ Board's regulations, Elizabeth Whiteman of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is January 13, 2023. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to January 30, 2023.

A copy of the application will be available for public inspection in the "Online FTZ Information Section" section of the FTZ Board's website, which is accessible via www.trade.gov/ftz. For further information, contact Elizabeth Whiteman at Elizabeth.Whiteman@trade.gov.

Dated: November 7, 2022.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2022-24709 Filed 11-10-22; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Order Renewing Order Temporarily Denying Export Privileges

Mahan Airways, Mahan Tower, No. 21, Azadegan St., M.A. Jenah Exp. Way, Tehran, Iran;

Pejman Mahmood Kosarayanifard, a/k/a Kosarian Fard, P.O. Box 52404, Dubai, United Arab Emirates;

Mahmoud Amini, G#22 Dubai Airport Free Zone, P.O. Box 393754, Dubai, United Arab Emirates and P.O. Box 52404, Dubai, United Arab Emirates and Mohamed Abdulla Alqaz Building, Al Maktoum Street, Al Rigga, Dubai, United Arab Emirates:

Kerman Aviation, a/k/a GIE Kerman Aviation, 42 Avenue Montaigne 75008, Paris. France:

Sirjanco Trading LLC, P.O. Box 8709, Dubai, United Arab Emirates;

Mahan Air General Trading LLC, 19th Floor Al Moosa Tower One, Sheik Zayed Road, Dubai 40594, United Arab Emirates;

Mehdi Bahrami, Mahan Airways- Istanbul Office, Cumhuriye Cad. Sibil Apt No: 101 D:6, 34374 Emadad, Sisli Istanbul, Turkey; Al Naser Airlines, a/k/a al-Naser Airlines, a/

k/a Al Naser Wings Airline, a/k/a Alnaser Airlines and Air Freight Ltd., Home 46, Al-Karrada, Babil Region, District 929, St 21, Beside Al Jadirya Private Hospital, Baghdad, Iraq and Al Amirat Street, Section 309, St. 3/H.20, Al Mansour, Baghdad, Iraq and P.O. Box 28360, Dubai, United Arab Emirates and P.O. Box 911399, Amman 11191, Jordan;

Ali Abdullah Alhay, a/k/a Ali Alhay, a/k/a Ali Abdullah Ahmed Alhay, Home 46, Al-Karrada, Babil Region, District 929, St 21, Beside Al Jadirya Private Hospital, Baghdad, Iraq and Anak Street, Qatif, Saudi Arabia 61177;

Bahar Safwa General Trading, P.O. Box 113212, Citadel Tower, Floor-5, Office #504, Business Bay, Dubai, United Arab Emirates and P.O. Box 8709, Citadel Tower, Business Bay, Dubai, United Arab Emirates;

Sky Blue Bird Group, a/k/a Sky Blue Bird Aviation, a/k/a Sky Blue Bird Ltd., a/k/a Sky Blue Bird FZC, P.O. Box 16111, Ras Al Khaimah Trade Zone, United Arab Emirates;

Issam Shammout, a/k/a Muhammad Isam Muhammad Anwar Nur Shammout, a/k/a Issam Anwar, Philips Building, 4th Floor, Al Fardous Street, Damascus, Syria and Al Kolaa, Beirut, Lebanon 151515 and 17–18 Margaret Street, 4th Floor, London, W1W 8RP, United Kingdom and Cumhuriyet Mah. Kavakli San St. Fulya, Cad. Hazar Sok. No.14/A Silivri, Istanbul, Turkey; Pursuant to Section 766.24 of the Export Administration Regulations, 15 CFR parts 730–774 (2021) ("EAR" or "the Regulations"), I hereby grant the request of the Office of Export Enforcement ("OEE") to renew the temporary denial order issued in this matter on May 13, 2022. I find that renewal of this order, as modified, is necessary in the public interest to prevent an imminent violation of the Regulations.¹

I. Procedural History

On March 17, 2008, Darryl W. Jackson, the then-Assistant Secretary of Commerce for Export Enforcement ("Assistant Secretary"), signed an order denying Mahan Airways' export privileges for a period of 180 days on the ground that issuance of the order was necessary in the public interest to prevent an imminent violation of the Regulations. The order also named as denied persons Blue Airways, of Yerevan, Armenia ("Blue Airways of Armenia"), as well as the "Balli Group Respondents," namely, Balli Group PLC, Balli Aviation, Balli Holdings, Vahid Alaghband, Hassan Alaghband, Blue Sky One Ltd., Blue Sky Two Ltd., Blue Sky Three Ltd., Blue Sky Four Ltd., Blue Sky Five Ltd., and Blue Sky Six Ltd., all of the United Kingdom. The order was issued ex parte pursuant to Section 766.24(a) of the Regulations, and went into effect on March 21, 2008, the date it was published in the Federal Register.

This temporary denial order ("TDO") was renewed in accordance with Section 766.24(d) of the Regulations.²

¹ The Regulations, currently codified at 15 CFR parts 730-774 (2021), originally issued pursuant to the Export Administration Act (50 U.S.C. 4601-4623 (Supp. III 2015)) ("EAA"), which lapsed on August 21, 2001. The President, through Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), as extended by successive Presidential Notices, continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701, et seq. (2012)) ("IEEPA"). On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, 50 U.S.C. 4801-4852 ("ECRA"). While Section 1766 of ECRA repeals the provisions of the EAA (except for three sections which are inapplicable here), Section 1768 of ECRA provides, in pertinent part, that all orders, rules, regulations, and other forms of administrative action that were made or issued under the EAA, including as continued in effect pursuant to IEEPA, and were in effect as of ECRA's date of enactment (August 13, 2018), shall continue in effect according to their terms until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA. Moreover, Section 1761(a)(5) of ECRA authorizes the issuance of temporary denial orders.

² Section 766.24(d) provides that BIS may seek renewal of a temporary denial order for additional

Continued

Subsequent renewals also have issued pursuant to Section 766.24(d), including most recently on May 13, 2022.³ Some of the renewal orders and the modification orders that have issued between renewals have added certain parties as respondents or as related persons, or effected the removal of certain parties.⁴

The September 11, 2009 renewal order continued the denial order as to Mahan Airways, but not as to the Balli Group Respondents or Blue Airways of Armenia.⁵ As part of the February 25, 2011 renewal order, Pejman Mahmood

180-day renewal periods, if it believes that renewal is necessary in the public interest to prevent an imminent violation. Renewal requests are to be made in writing no later than 20 days before the scheduled expiration date of a temporary denial order. Renewal requests may include discussion of any additional or changed circumstances, and may seek appropriate modifications to the order, including the addition of parties as respondents or related persons, or the removal of parties previously added as respondents or related persons. BIS is not required to seek renewal as to all parties, and a removal of a party can be effected if, without more, BIS does not seek renewal as to that party. Any party included or added to a temporary denial order as a respondent may oppose a renewal request as set forth in Section 766.24(d). Parties included or added as related persons can at any time appeal their inclusion as a related person, but cannot challenge the underlying temporary denial order, either as initially issued or subsequently renewed, and cannot oppose a renewal request. See also note

³ The May 13, 2022 renewal order was effective upon issuance and published in the Federal Register on May 18, 2022 (87 FR 30,173). Prior renewal orders issued on September 17, 2008, March 16, 2009, September 11, 2009, March 9, 2010, September 3, 2010, February 25, 2011, August 24, 2011, February 15, 2012, August 9, 2012, February 4, 2013, July 31, 2013, January 24, 2014, July 22, 2014, January 16, 2015, July 13, 2015, January 7, 2016, July 7, 2016, December 30, 2016, June 27, 2017, December 20, 2017, June 14, 2018, December 11, 2018, June 5, 2019, May 29, 2020, November 24, 2020, May 21, 2021, November 17, 2021, and May 13, 2022, respectively. The August 24, 2011 renewal followed the issuance of a modification order that issued on July 1, 2011, to add Zarand Aviation as a respondent. The July 13, 2015 renewal followed a modification order that issued May 21, 2015, and added Al Naser Airlines, Ali Abdullah Alhay, and Bahar Safwa General Trading as respondents. Each of the renewal orders and each of the modification orders referenced in this footnote or elsewhere in this order has been published in the Federal Register.

⁴ Pursuant to Sections 766.23 and 766.24(c) of the Regulations, any person, firm, corporation, or business organization related to a denied person by affiliation, ownership, control, or position of responsibility in the conduct of trade or related services may be added as a "related person" to a temporary denial order to prevent evasion of the order.

⁵ Balli Group PLC and Balli Aviation settled proposed BIS administrative charges as part of a settlement agreement that was approved by a settlement order issued on February 5, 2010. The sanctions imposed pursuant to that settlement and order included, *inter alia*, a \$15 million civil penalty and a requirement to conduct five external audits and submit related audit reports. The Balli Group Respondents also settled related charges with the Department of Justice and the Treasury Department's Office of Foreign Assets Control.

Kosarayanifard (a/k/a Kosarian Fard), Mahmoud Amini, and Gatewick LLC (a/k/a Gatewick Freight and Cargo Services, a/k/a Gatewick Aviation Services) were added as related persons to prevent evasion of the TDO.⁶ A modification order issued on July 1, 2011, adding Zarand Aviation as a respondent in order to prevent an imminent violation.⁷

As part of the August 24, 2011 renewal, Kerman Aviation, Sirjanco Trading LLC, and Ali Eslamian were added as related persons. Mahan Air General Trading LLC, Equipco (UK) Ltd., and Skyco (UK) Ltd. were added as related persons by a modification order issued on April 9, 2012. Mehdi Bahrami was added as a related person as part of the February 4, 2013 renewal order.

On May 21, 2015, a modification order issued adding Al Naser Airlines, Ali Abdullah Alhay, and Bahar Safwa General Trading as respondents. As detailed in that order and discussed further *infra*, these respondents were added to the TDO based upon evidence that they were acting together to, *inter alia*, obtain aircraft subject to the Regulations for export or reexport to Mahan in violation of the Regulations and the TDO.

Sky Blue Bird Group and its chief executive officer, Issam Shammout, were added as related persons as part of the July 13, 2015 renewal order.⁸ On November 16, 2017, a modification order issued to remove Ali Eslamian, Equipco (UK) Ltd., and Skyco (UK) Ltd. as related persons following a request by OEE for their removal.⁹

The December 11, 2018 renewal order continued the denial of the export privileges of Mahan Airways, Pejman Mahmood Kosarayanifard, Mahmoud Amini, Kerman Aviation, Sirjanco Trading LLC, Mahan Air General Trading LLC, Mehdi Bahrami, Al Naser Airlines, Ali Abdullah Alhay, Bahar Safwa General Trading, Sky Blue Bird Group, and Issam Shammout.

On October 18, 2022, BIS, through OEE, submitted a written request for renewal of the TDO that issued on May 13, 2022. The written request was made more than 20 days before the TDO's scheduled expiration. Notice of the renewal request was provided to Mahan Airways, Al Naser Airlines, Ali Abdullah Alhay, and Bahar Safwa General Trading in accordance with Sections 766.5 and 766.24(d) of the Regulations. No opposition to the renewal of the TDO has been received. Furthermore, no appeal of the related person determinations made as part of the September 3, 2010, February 25, 2011, August 24, 2011, April 9, 2012, February 4, 2013, and July 13, 2015 renewal or modification orders has been made by Kosarian Fard, Mahmoud Amini, Kerman Aviation, Sirjanco Trading LLC, Mahan Air General Trading LLC, Mehdi Bahrami, Sky Blue Bird Group, or Issam Shammout.¹⁰

II. Renewal of the TDO

A. Legal Standard

Pursuant to Section 766.24, BIS may issue or renew an order temporarily denying a respondent's export privileges upon a showing that the order is necessary in the public interest to prevent an "imminent violation" of the Regulations. 15 CFR 766.24(b)(1) and 766.24(d). "A violation may be "imminent" either in time or degree of likelihood." 15 CFR 766.24(b)(3). BIS may show "either that a violation is about to occur, or that the general circumstances of the matter under

⁶ See note 4, supra, concerning the addition of related persons to a temporary denial order. Kosarian Fard and Mahmoud Amini remain parties to the TDO. On August 13, 2014, BIS and Gatewick resolved administrative charges against Gatewick, including a charge for acting contrary to the terms of a BIS denial order (15 CFR 764.2(k)). In addition to the payment of a civil penalty, the settlement includes a seven-year denial order. The first two years of the denial period were active, with the remaining five years suspended conditioned upon Gatewick's full and timely payment of the civil penalty and its compliance with the Regulations during the seven-year denial order period. This denial order, in effect, superseded the TDO as to Gatewick, which was not included as part of the January 16, 2015 renewal order. The Gatewick LLC Final Order was published in the Federal Register on August 20, 2014. See 79 FR 49,283 (Aug. 20, 2014).

⁷ Zarand Aviation's export privileges remained denied until July 22, 2014, when it was not included as part of the renewal order issued on that date.

⁸ The U.S. Department of the Treasury's Office of Foreign Assets Control ("OFAC") designated Sky Blue Bird and Issam Shammout as Specially Designated Global Terrorists ("SDGTs") on May 21, 2015, pursuant to Executive Order 13224, for "providing support to Iran's Mahan Air." See 80 FR 30,762 (May 29, 2015).

⁹The November 16, 2017 modification was published in the **Federal Register** on December 4,

^{2017.} See 82 FR 57,203 (Dec. 4, 2017). On September 28, 2017, BIS and Ali Eslamian resolved an administrative charge for acting contrary to the terms of the denial order (15 CFR 764.2(k)) that was based upon Eslamian's violation of the TDO after his addition to the TDO on August 24, 2011. Equipco (UK) Ltd., and Skyco (UK) Ltd., two companies owned and operated by Eslamian, also were parties to the settlement agreement and were added to the settlement order as related persons. In addition to other sanctions, the settlement provides that Eslamian, Equipco, and Skyco shall be subject to a conditionally suspended denial order for a period of four years from the date of the settlement order.

¹⁰ A party named or added as a related person may not oppose the issuance or renewal of the underlying temporary denial order, but may file an appeal of the related person determination in accordance with Section 766.23(c). See also note 2, suppa

investigation or case under criminal or administrative charges demonstrate a likelihood of future violations." *Id.* As to the likelihood of future violations, BIS may show that the violation under investigation or charge "is significant, deliberate, covert and/or likely to occur again, rather than technical or negligent [.]" *Id.* A "lack of information establishing the precise time a violation may occur does not preclude a finding that a violation is imminent, so long as there is sufficient reason to believe the likelihood of a violation." *Id.*

B. The TDO and BIS's Requests for Renewal

OEE's request for renewal is based upon the facts underlying the issuance of the initial TDO, and the renewal and modification orders subsequently issued in this matter, including the May 21, 2015 modification order and the renewal order issued on May 21, 2021, and the evidence developed over the course of this investigation, which indicate a blatant disregard of U.S. export controls and the TDO. The initial TDO was issued as a result of evidence that showed that Mahan Airways and other parties engaged in conduct prohibited by the EAR by knowingly reexporting to Iran three U.S.-origin aircraft, specifically Boeing 747s ("Aircraft 1-3"), items subject to the EAR and classified under Export Control Classification Number ("ECCN") 9A991.b, without the required U.S. Government authorization. Further evidence submitted by BIS indicated that Mahan Airways was involved in the attempted re-export of three additional U.S.-origin Boeing 747s ("Aircraft 4-6")

As discussed in the September 17, 2008 renewal order, evidence presented by BIS indicated that Aircraft 1-3 continued to be flown on Mahan Airways' routes after issuance of the TDO, in violation of the Regulations and the TDO itself.¹¹ It also showed that Aircraft 1–3 had been flown in further violation of the Regulations and the TDO on the routes of Iran Air, an Iranian Government airline, Moreover, as discussed in the March 16, 2009, September 11, 2009 and March 9, 2010 renewal orders, Mahan Airways registered Aircraft 1–3 in Iran, obtained Iranian tail numbers for them (EP-MNA, EP-MNB, and EP-MNE, respectively), and continued to operate at least two of them in violation of the Regulations and the TDO,12 while also committing an

additional knowing and willful violation when it negotiated for and acquired an additional U.S.-origin aircraft. The additional acquired aircraft was an MD–82 aircraft, which subsequently was painted in Mahan Airways' livery and flown on multiple Mahan Airways' routes under tail number TC–TUA.

The March 9, 2010 renewal order also noted that a court in the United Kingdom ("U.K.") had found Mahan Airways in contempt of court on February 1, 2010, for failing to comply with that court's December 21, 2009 and January 12, 2010 orders compelling Mahan Airways to remove the Boeing 747s from Iran and ground them in the Netherlands. Mahan Airways and the Balli Group Respondents had been litigating before the U.K. court concerning ownership and control of Aircraft 1–3. In a letter to the U.K. court dated January 12, 2010, Mahan Airways' Chairman indicated, inter alia, that Mahan Airways opposes U.S. Government actions against Iran, that it continued to operate the aircraft on its routes in and out of Tehran (and had 158,000 "forward bookings" for these aircraft), and that it wished to continue to do so and would pay damages if required by that court, rather than ground the aircraft.

The September 3, 2010 renewal order discussed the fact that Mahan Airways' violations of the TDO extended beyond operating U.S.-origin aircraft and attempting to acquire additional U.S.origin aircraft. In February 2009, while subject to the TDO, Mahan Airways participated in the export of computer motherboards, items subject to the Regulations and designated as EAR99, from the United States to Iran, via the United Arab Emirates ("UAE"), in violation of both the TDO and the Regulations, by transporting and/or forwarding the computer motherboards from the UAE to Iran. Mahan Airways' violations were facilitated by Gatewick LLC, which not only participated in the transaction, but also has stated to BIS that it acted as Mahan Airways' sole booking agent for cargo and freight forwarding services in the UAE.

Moreover, in a January 24, 2011 filing in the U.K. court, Mahan Airways asserted that Aircraft 1–3 were not being used, but stated in pertinent part that the aircraft were being maintained in Iran "in an airworthy condition" and that, depending on the outcome of its U.K. court appeal, the aircraft "could immediately go back into service . . . on international routes into and out of

not have been operational at the time of the March 9, 2010 renewal order. $\,$

Iran." Mahan Airways' January 24, 2011 submission to U.K. Court of Appeal, at p. 25, ¶¶ 108, 110. This clearly stated intent, both on its own and in conjunction with Mahan Airways' prior misconduct and statements, demonstrated the need to renew the TDO in order to prevent imminent future violations. Two of these three 747s subsequently were removed from Iran and are no longer in Mahan Airways' possession. The third of these 747s remained in Iran under Mahan's control. Pursuant to Executive Order 13224, this 747 was designated a Specially Designated Global Terrorist ("SDGT") by the U.S. Department of the Treasury's Office of Foreign Assets Control ("OFAC") on September 19, 2012.13 Furthermore, as discussed in the February 4, 2013 Order, open source information indicated that this 747, painted in the livery and logo of Mahan Airways, had been flown between Iran and Syria, and was suspected of ferrying weapons and/or other equipment to the Syrian Government from Iran's Islamic Revolutionary Guard Corps.

In addition, as first detailed in the July 1, 2011 and August 24, 2011 orders, and discussed in subsequent renewal orders in this matter, Mahan Airways also continued to evade U.S. export control laws by operating two Airbus A310 aircraft, bearing Mahan Airways' livery and logo, on flights into and out of Iran. 14 At the time of the July 1, 2011 and August 24, 2011 orders, these Airbus A310s were registered in France, with tail numbers F-OJHH and F-OJHI, respectively. 15 The August 2012 renewal order also found that Mahan Airways had acquired another Airbus A310 aircraft subject to the Regulations, with MSN 499 and Iranian tail number EP-VIP, in violation of the

¹¹ Engaging in conduct prohibited by a denial order violates the Regulations. 15 CFR 764.2(a) and (k).

 $^{^{12}}$ The third Boeing 747 appeared to have undergone significant service maintenance and may

¹³ See http://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/pages/ 20120919.aspx.

¹⁴ The Airbus A310s are powered with U.S.-origin engines. The engines are subject to the Regulations and classified under Export Control Classification ("ECCN") 9A991.d. The Airbus A310s contain controlled U.S.-origin items valued at more than 10 percent of the total value of the aircraft and as a result are subject to the Regulations. They are classified under ECCN 9A991.b. The export or reexport of these aircraft to Iran requires U.S. Government authorization pursuant to Sections 742.8 and 746.7 of the Regulations.

¹⁵ OEE subsequently presented evidence that after the August 24, 2011 renewal, Mahan Airways worked along with Kerman Aviation and others to de-register the two Airbus A310 aircraft in France and to register both aircraft in Iran (with, respectively, Iranian tail numbers EP–MHH and EP–MHI). It was determined subsequent to the February 15, 2012 renewal order that the registration switch for these A310s was cancelled and that Mahan Airways then continued to fly the aircraft under the original French tail numbers (F–OJHH and F–OJHI, respectively). Both aircraft apparently remain in Mahan Airways' possession.

Regulations. ¹⁶ On September 19, 2012, all three Airbus A310 aircraft (tail numbers F–OJHH, F–OJHI, and EP–VIP) were designated as SDGTs. ¹⁷

The February 4, 2013 renewal order laid out further evidence of continued and additional efforts by Mahan Airways and other persons acting in concert with Mahan, including Kral Aviation and another Turkish company, to procure U.S.-origin engines—two GĚ CF6-50C2 engines, with MSNs 517621 and 517738, respectively—and other aircraft parts in violation of the TDO and the Regulations. 18 The February 4, 2013 order also added Mehdi Bahrami as a related person in accordance with Section 766.23 of the Regulations. Bahrami, a Mahan Vice-President and the head of Mahan's Istanbul Office, also was involved in Mahan's acquisition of the original three Boeing 747s (Aircraft 1–3) that resulted in the original TDO, and has had a business relationship with Mahan dating back to

The July 31, 2013 renewal order detailed additional evidence obtained by OEE showing efforts by Mahan Airways to obtain another GE CF6–50C2 aircraft engine (MSN 528350) from the United States via Turkey. Multiple Mahan employees, including Mehdi Bahrami, were involved in or aware of matters related to the engine's arrival in Turkey from the United States, plans to visually inspect the engine, and prepare it for shipment from Turkey.

Mahan Airways sought to obtain this U.S.-origin engine through Pioneer Logistics Havacilik Turizm Yonetim Danismanlik ("Pioneer Logistics"), an

On December 31, 2013, Kral Aviation was added to BIS's Entity List, Supplement No. 4 to Part 744 of the Regulations. See 78 FR 75,458 (Dec. 12, 2013). Companies and individuals are added to the Entity List for engaging in activities contrary to the national security or foreign policy interests of the United States. See 15 CFR 744.11.

aircraft parts supplier located in Turkey, and its director/operator, Gulnihal Yegane, a Turkish national who previously had conducted Mahan related business with Mehdi Bahrami and Ali Eslamian. Moreover, as referenced in the July 31, 2013 renewal order, a sworn affidavit by Kosol Surinanda, also known as Kosol Surinandha, Managing Director of Mahan's General Sales Agent in Thailand, stated that the shares of Pioneer Logistics for which he was the listed owner were "actually the property of and owned by Mahan." He further stated that he held "legal title to the shares until otherwise required by Mahan" but would "exercise the rights granted to [him] exactly and only as instructed by Mahan and [his] vote and/ or decisions [would] only and exclusively reflect the wills and demands of Mahan[.]" 19

The January 24, 2014 renewal order outlined OEE's continued investigation of Mahan Airways' activities and detailed an attempt by Mahan, which OEE thwarted, to obtain, via an Indonesian aircraft parts supplier, two U.S.-origin Honeywell ALF-502R-5 aircraft engines (MSNs LF5660 and LF5325), items subject to the Regulations, from a U.S. company located in Texas. An invoice of the Indonesian aircraft parts supplier dated March 27, 2013, listed Mahan Airways as the purchaser of the engines and included a Mahan ship-to address. OEE also obtained a Mahan air waybill dated March 12, 2013, listing numerous U.S.origin aircraft parts subject to the Regulations—including, among other items, a vertical navigation gyroscope, a transmitter, and a power control unitbeing transported by Mahan from Turkey to Iran in violation of the TDO.

The July 22, 2014 renewal order discussed open source evidence from the March-June 2014 time period regarding two BAE regional jets, items subject to the Regulations, that were painted in the livery and logo of Mahan Airways and operating under Iranian tail numbers EP–MOI and EP–MOK, respectively. In addition, aviation industry resources indicated that these

aircraft were obtained by Mahan Airways in late November 2013 and June 2014, from Ukrainian Mediterranean Airline, a Ukrainian airline that was added to BIS's Entity List (Supplement No. 4 to Part 744 of the Regulations) on August 15, 2011, for acting contrary to the national security and foreign policy interests of the United States.²¹ Open source information indicated that at least EP–MOI remained active in Mahan's fleet, and that the aircraft was being operated on multiple flights in July 2014.

The January 16, 2015 renewal order detailed evidence of additional attempts by Mahan Airways to acquire items subject the Regulations in further violation of the TDO. Specifically, in March 2014. OEE became aware of an inertial reference unit bearing serial number 1231 ("the IRU") that had been sent to the United States for repair. The IRU is a U.S.-origin item, subject to the Regulations, classified under ECCN 7A103, and controlled for missile technology reasons. Upon closer inspection, it was determined that IRU came from or had been installed on an Airbus A340 aircraft bearing MSN 056. Further investigation revealed that as of approximately February 2014, this aircraft was registered under Iranian tail number EP-MMB and had been painted in the livery and logo of Mahan Airwavs.

The January 16, 2015 renewal order also described related efforts by the Departments of Justice and Treasury to further thwart Mahan's illicit procurement efforts. Specifically, on August 14, 2014, the United States Attorney's Office for the District of Maryland filed a civil forfeiture complaint for the IRU pursuant to 22 U.S.C. 401(b) that resulted in the court issuing an Order of Forfeiture on December 2, 2014. EP-MMB remains listed as active in Mahan Airways' fleet and has been used on flights into and out of Iran as recently as December 19, 2017.

Additionally, on August 29, 2014, OFAC blocked the property and interests in property of Asian Aviation Logistics of Thailand, a Mahan Airways

 $^{^{16}\,}See$ note 14, supra.

¹⁷ See http://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/pages/
20120919.aspx. Mahan Airways was previously designated by OFAC as a SDGT on October 18, 2011. 77 FR 64,427 (October 18, 2011).

¹⁸ Kral Aviation was referenced in the February 4, 2013 renewal order as "Turkish Company No. 1." Kral Aviation purchased a GE CF6-50C2 aircraft engine (MSN 517621) from the United States in July 2012, on behalf of Mahan Airways. OEE was able to prevent this engine from reaching Mahan by issuing a redelivery order to the freight forwarder in accordance with Section 758.8 of the Regulations. OEE also issued Kral Aviation a redelivery order for the second CF6-50C2 engine (MSN 517738) on July 30, 2012. The owner of the second engine subsequently cancelled the item's sale to Kral Aviation. In September 2012, OEE was alerted by a U.S. exporter that another Turkish company ("Turkish Company No. 2") was attempting to purchase aircraft spare parts intended for re-export by Turkish Company No. 2 to Mahan Airways, See February 4, 2013 renewal order.

¹⁹ Pioneer Logistics, Gulnihal Yegane, and Kosol Surinanda also were added to the Entity List on December 12, 2013. *See* 78 FR 75,458 (Dec. 12, 2013).

²⁰ The BAE regional jets are powered with U.S.-origin engines. The engines are subject to the EAR and classified under ECCN 9A991.d. These aircraft contain controlled U.S.-origin items valued at more than 10 percent of the total value of the aircraft and as a result are subject to the EAR. They are classified under ECCN 9A991.b. The export or reexport of these aircraft to Iran requires U.S. Government authorization pursuant to Sections 742.8 and 746.7 of the Regulations.

²¹ See 76 FR 50,407 (Aug. 15, 2011). The July 22, 2014 renewal order also referenced two Airbus A320 aircraft painted in the livery and logo of Mahan Airways and operating under Iranian tail numbers EP–MMK and EP–MML, respectively. OEE's investigation also showed that Mahan obtained these aircraft in November 2013, from Khors Air Company, another Ukrainian airline that, like Ukrainian Mediterranean Airlines, was added to BIS's Entity List on August 15, 2011. Open source evidence indicates the two Airbus A320 aircraft may have been transferred by Mahan Airways to another Iranian airline in October 2014, and issued Iranian tail numbers EP–APE and EP–APF, respectively.

affiliate or front company, pursuant to Executive Order 13224. In doing so, OFAC described Mahan Airways' use of Asian Aviation Logistics to evade sanctions by making payments on behalf of Mahan for the purchase of engines and other equipment.²²

The May 21, 2015 modification order detailed the acquisition of two aircraft, specifically an Airbus A340 bearing MSN 164 and an Airbus A321 bearing MSN 550, that were purchased by Al Naser Airlines in late 2014/early 2015 and were under the possession, control, and/or ownership of Mahan Airways.23 The sales agreements for these two aircraft were signed by Ali Abdullah Alhay for Al Naser Airlines.²⁴ Payment information reveals that multiple electronic funds transfers ("EFT") were made by Ali Abdullah Alhay and Bahar Safwa General Trading in order to acquire MSNs 164 and 550. The May 21, 2015 modification order also laid out evidence showing the respondents' attempts to obtain other controlled aircraft, including aircraft physically located in the United States in similarlypatterned transactions during the same recent time period. Transactional documents involving two Airbus A320s bearing MSNs 82 and 99, respectively, again showed Ali Abdullah Alhay signing sales agreements for Al Naser Airlines.²⁵ A review of the payment

information for these aircraft similarly revealed EFTs from Ali Abdullah Alhay and Bahar Safwa General Trading that follow the pattern described for MSNs 164 and 550, *supra*. MSNs 82 and 99 were detained by OEE Special Agents prior to their planned export from the United States.

The July 13, 2015 renewal order outlined evidence showing that Al Naser Airlines' attempts to acquire aircraft on behalf of Mahan Airways extended beyond MSNs 164 and 550 to include a total of nine aircraft.²⁶ Four of the aircraft, all of which are subject to the Regulations and were obtained by Mahan from Al Naser Airlines, had been issued the following Iranian tail numbers: EP-MMD (MSN 164), EP-MMG (MSN 383), EP-MMH (MSN 391) and EP-MMR (MSN 416), respectively.27 Publicly available flight tracking information provided evidence that at the time of the July 13, 2015 renewal, both EP-MMH and EP-MMR were being actively flown on routes into and out of Iran in violation of the Regulations.²⁸ The January 7, 2016 renewal order discussed evidence that Mahan Airways had begun actively flying EP-MMD on international routes into and out of Iran. Additionally, the January 7, 2016 order described publicly available aviation database and flight tracking information indicating that Mahan Airways continued efforts to acquire Iranian tail numbers and press into active service under Mahan's livery

and logo at least two more of the Airbus A340 aircraft it had obtained from or through Al Naser Airlines: EP–MME (MSN 371) and EP–MMF (MSN 376), respectively.

The July 7, 2016 renewal order described Mahan Airways' acquisition of a BAE Avro RJ–85 aircraft (MSN 2392) in violation of the Regulations and its subsequent registration under Iranian tail number EP–MOR.²⁹ This information was corroborated by publicly available information on the website of Iran's civil aviation authority. The July 7, 2016 order also outlined Mahan's continued operation of EP–MMF in violation of the Regulations on routes from Tehran, Iran to Beijing, China and Shanghai, China, respectively.

The December 30, 2016 renewal order outlined Mahan's continued operation of multiple Airbus aircraft, including EP–MMD (MSN 164), EP–MMF (MSN 376), and EP–MMH (MSN 391), which were acquired from or through Al Naser Airlines, as previously detailed in pertinent part in the July 13, 2015 and January 7, 2016 renewal orders. Publicly available flight tracking information showed that the aircraft were operated on flights into and out of Iran, including from/to Beijing, China, Kuala Lumpur, Malaysia, and Istanbul, Turkey. 30

The June 27, 2017 renewal order included similar evidence regarding Mahan Airways' operation of multiple Airbus aircraft subject to the Regulations, including, but not limited to, aircraft procured from or through Al Naser Airlines, on flights into and out of Iran, including from/to Moscow, Russia, Shanghai, China and Kabul, Afghanistan. The June 27, 2017 order also detailed evidence concerning a suspected planned or attempted diversion to Mahan of an Airbus A340 subject to the Regulations that had first been mentioned in OEE's December 13, 2016 renewal request.

The December 20, 2017 renewal order presented evidence that a Mahan

²² See http://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/Pages/ 20140829.aspx. See 79 FR 55,073 (Sep. 15, 2014). OFAC also blocked the property and property interests of Pioneer Logistics of Turkey on August 29, 2014. Id. Mahan Airways' use of Pioneer Logistics in an effort to evade the TDO and the Regulations was discussed in a prior renewal order, as summarized, supra, at 14. BIS added both Asian Aviation Logistics and Pioneer Logistics to the Entity List on December 12, 2013. See 78 FR 75,458 (Dec. 12, 2013).

²³ Both of these aircraft are powered by U.S.-origin engines that are subject to the Regulations and classified under ECCN 9A991.d. Both aircraft contain controlled U.S.-origin items valued at more than 10 percent of the total value of the aircraft and as a result are subject to the EAR regardless of their location. The aircraft are classified under ECCN 9A991.b. The export or re-export of these aircraft to Iran requires U.S. Government authorization pursuant to Sections 742.8 and 746.7 of the Regulations.

 $^{^{24}\,\}mathrm{The}$ evidence obtained by OEE showed Ali Abdullah Alhay as a 25% owner of Al Naser Airlines.

²⁵ Both aircraft were physically located in the United States and therefore are subject to the Regulations pursuant to Section 734.3(a)(1). Moreover, these Airbus A320s are powered by U.S.-origin engines that are subject to the Regulations and classified under Export Control Classification Number ECCN 9A991.d. The Airbus A320s contain controlled U.S.-origin items valued at more than 10 percent of the total value of the aircraft and as a result are subject to the EAR regardless of their location. The aircraft are classified under ECCN 9A991.b. The export or re-export of these aircraft to Iran requires U.S. Government authorization pursuant to Sections 742.8 and 746.7 of the Regulations.

²⁶ This evidence included a press release dated May 9, 2015, that appeared on Mahan Airways website and stated that Mahan "added 9 modern aircraft to its air fleet [,]" and that the newly acquired aircraft included eight Airbus A340s and one Airbus A321. See http://www.mahan.aero/en/ mahan-air/press-room/44. The press release was subsequently removed from Mahan Airways website. Publicly available aviation databases similarly showed that Mahan had obtained nine additional aircraft from Al Naser Airlines in May 2015, including MSNs 164 and 550. As also discussed in the July 13, 2015 renewal order, Sky Blue Bird Group, via Issam Shammout, was actively involved in Al Naser Airlines' acquisition of MSNs 164 and 550, and the attempted acquisition of MSNs 82 and 99 (which were detained by OEE)

²⁷ The Airbus A340s are powered by U.S.-origin engines that are subject to the Regulations and classified under ECCN 9A991.d. The Airbus A340s contain controlled U.S.-origin items valued at more than 10 percent of the total value of the aircraft and as a result are subject to the EAR regardless of their location. The aircraft are classified under ECCN 9A991.b. The export or re-export of these aircraft to Iran requires U.S. Government authorization pursuant to Sections 742.8 and 746.7 of the Regulations.

²⁸There is some publicly available information indicating that the aircraft Mahan Airways is flying under Iranian tail number EP–MMR is now MSN 615, rather than MSN 416. Both aircraft are Airbus A340 aircraft that Mahan acquired from Al Naser Airlines in violation of the Regulations. Moreover, both aircraft were designated as SDGTs by OFAC on May 21, 2015, pursuant to Executive Order 13224. See 80 FR 30,762 (May 29, 2015).

²⁹ The BAE Avro RJ–85 is powered by U.S.-origin engines that are subject to the Regulations and classified under ECCN 9A991.d. The BAE Avro RJ–85 contains controlled U.S.-origin items valued at more than 10 percent of the total value of the aircraft and as a result is subject to the EAR regardless of its location. The aircraft is classified under ECCN 9A991.b, and its export or re-export to Iran requires U.S. Government authorization pursuant to Sections 742.8 and 746.7 of the Regulations.

³⁰ Specifically, on December 22, 2016, EP–MMD (MSN 164) flew from Dubai, UAE to Tehran, Iran. Between December 20 and December 22, 2016, EP–MMF (MSN 376) flew on routes from Tehran, Iran to Beijing, China and Istanbul, Turkey, respectively. Between December 26 and December 28, 2016, EP–MMH (MSN 391) flew on routes from Tehran, Iran to Kuala Lumpur, Malaysia.

employee attempted to initiate negotiations with a U.S. company for the purchase of an aircraft subject to the Regulations and classified under ECCN 9A610. Moreover, the order highlighted Al Naser Airlines' acquisition, via lease, of at least possession and/or control of a Boeing 737 (MSN 25361), bearing tail number YR-SEB, and an Airbus A320 (MSN 357), bearing tail number YR-SEA, from a Romanian company in violation of the TDO and the Regulations.³¹ Open source information indicates that after the December 20, 2017 renewal order publicly exposed Al Naser's acquisition of these two aircraft (MSNs 25361 and 357), the leases were subsequently cancelled and the aircraft returned to their owner.

The December 20, 2017 renewal order also included evidence indicating that Mahan Airways was continuing to operate a number of aircraft subject to the Regulations, including aircraft originally procured from or through Al Naser Airlines, on flights into and out of Iran, including from/to Lahore, Pakistan, Shanghai, China, Ankara, Turkey, Kabul, Afghanistan, and Baghdad, Iraq.

The June 14, 2018 renewal order outlined evidence that Mahan began actively operating EP–MMT, an Airbus A340 aircraft (MSN 292) acquired in 2017 and previously registered in Kazakhstan under tail number UP–A4003, on international flights into and out of Iran.³² It also discussed evidence that Mahan continued to operate a number of aircraft subject to the Regulations, including, but not limited to, EP–MME, EP–MMF, and EP–MMH, on international flights into and out of Iran, including from/to Beijing, China.

The June 14, 2018 renewal order also noted OFAC's May 24, 2018 designation of Otik Aviation, a/k/a Otik Havacilik Sanayi Ve Ticaret Limited Sirketi, of Turkey, as an SDGT pursuant to Executive Order 13224, for providing material support to Mahan, as well as OFAC's designation as SDGTs of an additional twelve aircraft in which Mahan has an interest.³³ The June 14, 2018 order also cited the April 2018 arrest and arraignment of a U.S. citizen on a three-count criminal information filed in the United States District Court for the District of New Jersey involving the unlicensed exports of U.S.-origin aircraft parts valued at over \$2 million to Iran, including to Mahan Airways.

The December 11, 2018 renewal order detailed publicly available information showing that Mahan Airways had continued operating a number of aircraft subject to the EAR, including, but not limited to, EP-MMB, EP-MME, EP-MMF, and EP-MMQ, on international flights into and out of Iran from/to Istanbul, Turkey, Guangzhou, China, Bangkok, Thailand, and Dubai, UAE.34 It also discussed that OEE's continued investigation of Mahan Airways and its affiliates and agents had resulted in an October 2018 guilty plea by Arzu Sagsoz, a Turkish national, in the U.S. District Court for the District of Columbia, stemming from her involvement in a conspiracy to export a U.S.-origin aircraft engine, valued at approximately \$810,000, to Mahan.

The December 11, 2018 order also noted OFAC's September 14, 2018 designation of Mahan-related entities as SDGTs pursuant to Executive Order 13224, namely, My Aviation Company Limited, of Thailand, and Mahan Travel and Tourism SDN BHD, a/k/a Mahan Travel a/k/a Mihan Travel & Tourism SDN BHD, of Malaysia.³⁵ As general

sales agents for Mahan Airways, these companies sold cargo space aboard Mahan Airways' flights, including on flights to Iran, and provided other services to or for the benefit of Mahan Airways and its operations.³⁶

The June 5, 2019 renewal order highlighted Mahan's continued violation of the TDO and the Regulations. An end-use check conducted by BIS in Malaysia in March 2019 uncovered evidence that, on approximately ten occasions, Mahan had caused, aided and/or abetted the unlicensed export of U.S.-origin items subject to the Regulations from the United States to Iran via Malaysia. The items included helicopter shafts, transmitters, and other aircraft parts, some of which are listed on the Commerce Control List and controlled on anti-terrorism grounds. The June 5, 2019 order also detailed publicly available flight tracking information showing that Mahan continued to unlawfully operate a number of aircraft subject to the EAR on flights into and out of Iran, including on routes to and from Damascus, Syria. 37

The June 5, 2019 order also described actions taken by both BIS and OFAC to thwart efforts by entities connected to or acting on behalf of Mahan Airways to violate U.S. export controls and sanctions related to Iran. On May 14, 2019, BIS added Manohar Nair, Basha Asmath Shaikh, and two co-located companies that they operate, Emirates Hermes General Trading and Presto Freight International, LLC, to the Entity List pursuant to Section 744.11 of the Regulations, including for engaging in activities to procure U.S.-origin items on Mahan's behalf.38 On January 24, 2019, OFAC designated as SDGTs Flight Travel LLC, which is Mahan's general service agent in Yerevan, Armenia, and Qeshm Fars Air, an Iranian airline

³¹ The Airbus A320 is powered with U.S.-origin engines, which are subject to the EAR and classified under Export Control Classification ("ECCN") 9A991.d. The engines are valued at more than 10 percent of the total value of the aircraft, which consequently is subject to the EAR. The aircraft is classified under ECCN 9A991.b, and its export or reexport to Iran would require U.S. Government authorization pursuant to Sections 742.8 and 746.7 of the Regulations.

³² The Airbus A340 is powered by U.S.-origin engines that are subject to the Regulations and classified under ECCN 9A991.d. The Airbus A340 contains controlled U.S.-origin items valued at more than 10 percent of the total value of the aircraft and as a result is subject to the Regulations regardless of its location. The aircraft is classified under ECCN 9A991.b. The export or re-export of this aircraft to Iran requires U.S. Government authorization pursuant to Sections 742.8 and 746.7 of the Regulations. On June 4, 2018, EP–MMT (MSN 292) flew from Bangkok, Thailand to Tehran, Iran.

 $^{^{33}\,}See$ 83 FR 27,828 (June 14, 2018). OFAC's related press release stated in part that "[o]ver the last several years. Otik Aviation has procured and delivered millions of dollars in aviation-related spare and replacement parts for Mahan Air, some of which are procured from the United States and the European Union. As recently as 2017, Otik Aviation continued to provide Mahan Air with replacement parts worth well over \$100,000 per shipment, such as aircraft brakes." The twelve additional Mahan-related aircraft that were designated are: EP-MMA (MSN 20), EP-MMB (MSN 56), EP-MMC (MSN 282), EP-MMJ (MSN 526), EP-MMV (MSN 2079), EP-MNF (MSN 547), EP-MOD (MSN 3162), EP-MOM (MSN 3165), EP-MOP (MSN 2257), EP-MOQ (MSN 2261), EP-MOR (MSN 2392), and EP-MOS (MSN 2347). See https:// home.treasury.gov/news/press-releases/sm0395. See also https://www.treasury.gov/resource-center/ sanctions/OFAC-Enforcement/Pages/

³⁴ Flight tracking information showed that on December 10, 2018, EP–MMB (MSN 56) flew from Istanbul, Turkey to Tehran, Iran, and EP–MME (MSN 371) flew from Guangzhou, China to Tehran, Iran. Additionally, on December 6, 2018, EP–MMF (MSN 376) flew from Bangkok, Thailand to Tehran, Iran, and on December 9, 2018, EP–MMQ (MSN 449) flew on routes between Dubai, United Arab Emirates and Tehran. Iran.

 $^{^{35}}$ See 83 FR 34,301 (July 19, 2018) (designation of Mahan Travel and Tourism SDN BHD on July 9, 2018), and 83 FR 53,359 (Oct. 22, 2018)

⁽designation of My Aviation Company Limited and updating of entry for Mahan Travel and Tourism SDN BHD on September 14, 2018).

³⁶ OFAC's press release concerning its designation of My Aviation Company Limited on September 14, 2018, states in part that "[t]his Thailand-based company has disregarded numerous U.S. warnings, issued publicly and delivered bilaterally to the Thai government, to sever ties with Mahan Air." My Aviation provides cargo services to Mahan Airways, including freight booking, and works with local freight forwarding entities to ship cargo on regularly scheduled Mahan Airways' flights to Tehran, Iran. My Aviation has also provided Mahan Airways with passenger booking services. See https://home.treasury.gov/news/press-releases/sm484.

³⁷ Specifically, on May 26, 2019, EP–MMJ (MSN 526) flew from Damascus, Syria to Tehran, Iran. In addition, on May 24, 2019, EP–MNF (MSN 547) flew on routes between Moscow, Russia and Tehran, and on May 23, 2019, EP–MMF (MSN 376) flew from Dubai, UAE to Tehran.

³⁸ See 84 FR 21,233 (May 14, 2019).

which operates two U.S.-origin Boeing 747s 39 and is owned or controlled by Mahan, and also linked to the Islamic Revolutionary Guard Corps-Qods Force (IRGC-OF).40

The December 2, 2019 renewal order noted that OEE's on-going investigation revealed that U.S.-origin passenger flight and database management software subject to the Regulations was provided to a company in Turkey and subsequently used to facilitate and service Mahan's operations into and out of Turkey in further violation of the

Regulations.

Additionally, open source information, including flight tracking data and news articles published in October 2019, showed that Mahan Airways was now operating a U.S.origin Boeing 747 on routes between Iranian airports in Tehran, Kish Island, and Mashhad. This aircraft, bearing Iranian tail number EP-MNB, appears to be one of the three aircraft that Mahan illegally acquired via Blue Airways of Armenia and U.K.-based Balli Group that resulted in the issuance of the original TDO.41 See supra at 10-12.

Evidence was also described in the December 2, 2019 renewal order showing that on or about November 11, 2019, Mahan caused, aided and/or abetted the unlicensed export of a U.S.origin atomic absorption spectrometer, an item subject to the Regulations, from the United States to Iran via the UAE. Finally, publicly available flight tracking information showed that Mahan continued to unlawfully operate a number of aircraft subject to the EAR on flights into and out of Iran, including on routes to and from Guangzhou, China, Istanbul, Turkey, and Kuala Lumpur, Malaysia.⁴²

The May 29, 2020 renewal order cited Mahan's operation of EP-MMD, EP-MMF, and EP–MMI, aircraft originally acquired from Al Naser Airlines, on international flights into and out of Iran from/to Bangkok, Thailand, Dubai, UAE, and Shanghai, China in violation of the TDO and EAR.43 The May 29, 2020 renewal order also detailed the indictment of Ali Abdullah Alhay and Issam Shammout, parties added to the TDO in May and July 2015, respectively, in the United States District Court for the District of Columbia. Alhay and Shammout were charged with, among other violations, conspiring to export aircraft and parts to Mahan in violation of export control laws and the embargo on Iran beginning around August 2012 through May 2015.

In addition to detailing the operation of multiple aircraft in violation of the Regulations,⁴⁴ the November 24, 2020 renewal order discussed a related TDO issued on August 19, 2020, denying for 180 days the export privileges of Indonesia-based PT MS Aero Support ("PTMS Aero"), PT Antasena Kreasi ("PTAK"), PT Kandiyasa Energi Utama ("PTKEU"), Sunarko Kuntjoro, Triadi Senna Kuntjoro, and Satrio Wiharjo Sasmito based on their involvement in the unlicensed export of aircraft parts to Mahan Airways—often in coordination with Mustafa Ovieci, a Mahan executive.45 These parties also facilitated the shipment of damaged Mahan parts to the United States for repair and subsequent export back to Iran in further violation of U.S. laws. In both instances, the fact that the items were destined to Iran/Mahan was concealed from U.S. companies, shippers, and freight forwarders.46

The November 24, 2020 renewal order also includes actions taken by other U.S. government agencies such as OFAC's August 19, 2020 designation of UAEbased Parthia Cargo, its CEO Amin

Mahdavi, and Delta Parts Supply FZC as SDGTs pursuant to Executive Order 13224 for providing "key parts and logistics services for Mahan Air The OFAC press release further states, in part, that Mahdavi "has directly coordinated the shipment of parts on behalf of Mahan Air." 47 In addition, Mahdavi and Parthia Cargo were indicted in the United States District Court for the District of Columbia for violating sanctions on Iran.48

Moreover, in October 2020, the U.S. District Court for the District of New Jersey sentenced Joyce Eliasbachus to 18 months of confinement based on her role in a conspiracy to export \$2 million dollars' worth of aircraft parts from the United States to Iran, including to Mahan Airways.49

The May 21, 2021 renewal order outlined Mahan's continued operation of a number of aircraft subject to the EAR, including, but not limited to, EP-MMH, EP-MMI, and EP-MMQ, on international flights into and out of Iran from/to Shanghai, China, and Dubai, United Arab Emirates, and Guangzhou, China, respectively.50

Open source news reporting also indicated that after five years of maintenance, Mahan Air is now operating EP-MNE, a Boeing 747 on domestic flights within Iran.⁵¹ In addition to this aircraft being one of the original three Boeing aircraft Mahan obtained in violation of the Regulations, any service or maintenance involving parts subject to the EAR would further violate the TDO.

The November 17, 2021 order details Mahan's continued operation of a number of aircraft subject to the EAR, including, but not limited to EP-MME, EP-MMJ, EP-MMQ, on flights into and out of Iran from/to Istanbul, Turkey, and Dubai, United Arab Emirates, and Shenzhen, China, respectively.52

Continued

 $^{^{39}}$ These 747s are registered in Iran with tail numbers EP-FAA and EP-FAB, respectively.

⁴⁰OFAC's press release concerning these designations states that Qeshm Fars Air was being designated for "being owned or controlled by Mahan Air, as well as for assisting in, sponsoring, or providing financial, material or technological support for, or financial or other services to or in support of, the IRGC-QF," and that Flight Travel LLC was being designated for "acting for or on behalf of Mahan Air." It further states, inter alia, that "Mahan Air employees fill Qeshm Fars Air management positions, and Mahan Air provides technical and operational support for Qeshm Fars Air, facilitating the airline's illicit operations." See https://home.treasury.gov/news/press-releases/ sm590. See also https://www.treasury.gov/resourcecenter/sanctions/OFAC-Enforcement/Pages/ 20190124.aspx.

⁴¹ The same open sources indicated this aircraft continued to operate on flights within Iran to include a May 11, 2020 flight from Tehran, Iran to Kerman, Iran.

⁴² Publicly available flight tracking information shows that on November 23, 2019, EP-MME (MSN 371) flew from Guangzhou, China to Tehran, Iran, and on November 21, 2019, EP-MMF (MSN 376) flew on routes between Istanbul, Turkey and

Tehran, Iran. Additionally, on November 20, 2019, EP-MMQ (MSN 449) flew from Kuala Lumpur, Malaysia, to Tehran, Iran.

⁴³ Publicly available flight tracking information shows that on May 8, 2020, EP-MMD (MSN 164) flew on routes between Bangkok, Thailand and Tehran, Iran, and on May 10, 2020, EP-MMF (MSN 376) flew on routes between Dubai, UAE and Tehran. In addition, on May 9, 2020, EP-MMI (MSN 416) flew on routes between Shanghai, China and Tehran

⁴⁴ Publicly available flight tracking information shows that on November 13, 2020, EP-MMQ (MSN 449) flew on routes between Istanbul, Turkey and Tehran, Iran, and on November 15, 2020, EP–MMI (MSN 416) flew on routes between Shenzhen, China and Tehran.

⁴⁵ See 85 FR 52,321 (Aug. 25, 2020).

 $^{^{\}rm 46}\,PTMS$ Aero, PTAK, PTKEU, and Sunarko Kuntjoro were each indicted in December 2019 on multiple counts related to this conspiracy in the United States District Court for the District of

⁴⁷ https://home.treasury.gov/news/press-releases/ sm1098.

⁴⁸ https://www.justice.gov/opa/pr/iraniannational-and-uae-business-organization-chargedcriminal-conspiracy-violate-iranian.

⁴⁹ Eliasbachus' arrest and arraignment were detailed in the June 14, 2018 renewal order, as described supra at 21.

 $^{^{50}}$ Publicly available flight tracking information shows that on May 14, 2021, EP-MMH (MSN 391) flew on routes between Shanghai, China and Tehran, Iran, and on May 13, 2021, EP–MMI (MSN 416) flew on routes between Dubai, United Arab Emirates and Tehran. In addition, on May 20, 2021, EP-MMQ (MSN 346) flew on routes between Guangzhou, China and Tehran.

⁵¹ https://simpleflying.com/mahan-air-747-300flies-again/.

⁵² Publicly available flight tracking information shows that on November 7, 2021, EP–MME (MSN 376) flew on routes between Istanbul, Turkey and Tehran, Iran, and on November 9, 2021, EP-MMJ (MSN 526) flew on routes between Dubai, United

Additionally, publicly available industry sources showed that EP–MMG (MSN 383), an aircraft that Mahan acquired from Al Naser Air in violation of both the TDO and Regulations, was in a maintenance, repair, overhaul ("MRO") status at Iran's Imam Khomeini International Airport in Tehran, Iran.

The May 13, 2022 renewal order outlines Mahan's continuing violation of the TDO and/or Regulations including, but not limited to the operation of EP-MME, EP-MNO, and EP–MMB on flights into and out of Iran from/to Moscow, Russia, Damascus, Syria, and Guangzhou, China, respectively.⁵³ Open source press reports also indicates that as of April 2022. Mahan Air increased its service into Moscow, Russia by adding two weekly flights to Moscow's Sheremetyevo Airport ("SVO") to its current service into Moscow's Vnukovo Airport ("VKO").54 Mahan flights into Russia after February 24, 2022 violated the stringent export controls imposed on aviation-related (e.g., Commerce Control List Categories 7 and 9) items to Russia in response to Russia's further invasion of Ukraine. These controls include a license requirement for the export, reexport or transfer (in-country) to Russia of any aircraft or aircraft parts specified in Export Control Classification Number (ECCN) 9A991 (Section 746.8(a)(1) of the EAR).55

The May 13, 2022 renewal order also cited OFAC's recent administrative enforcement action with an Australian freight forwarder resulting in a \$6,131,855 civil penalty, which resolved, in part, allegations of receiving 327 payments from Mahan that were processed through U.S. financial institutions or foreign branches of U.S. financial institutions in apparent violation of OFAC sanctions.⁵⁶

Mahan Air has continued to engage in conduct prohibited by the TDO and Regulations, including the Russiarelated export controls set out in Section 746.8 of the Regulations. On September

19, 2022, BIS publicly identified Mahan's EP-MEE aircraft for its unlicensed reexport to Russia in apparent violation of Section 746.8 of the Regulations.⁵⁷ Additionally, open source evidence shows that Mahan continues to operate EP-MME, EP-MMJ, and EP-MMQ, on flights into and out of Iran from/to Moscow, Russia, and Dubai, United Arab Emirates, respectively, without the requisite authorization. Publicly available flight tracking information shows that on October 9, 2022, EP-MME (MSN 376) flew on routes between Tehran, Iran and Moscow, Russia's VTO airport, and on October 26, 2022, EP-MMJ (MSN 526) flew on routes between Tehran, Iran and Moscow, Russia's SVO airport. On October 28, 2022, EP-MMQ (MSN 346) flew on routes between Dubai, United Arab Emirates and Tehran, Iran.

Further, on August 2, 2022, BIS took a related enforcement action against Venezuela-based cargo airline Empresa de Transporte Aéreocargo del Sur, S.A., a/k/a Aerocargo del Sur Transportation Company, a/k/a EMTRASUR ("EMTRASUR"), for acquiring custody and/or control from Mahan Air of a U.S.-origin Boeing 747 aircraft bearing manufacturer's serial number 23413 ("MSN 23413") in violation of the TDO.58 In or around October 2021, Mahan Air transferred custody and control of MSN 23413 to EMTRASUR's parent company, CONVIASA, 59 through an intermediary. Open source evidence, including flight tracking data, reveals the aircraft, which was operating under Iranian tail number EP-MND, was subsequently painted in EMTRASUR's livery and logo and bears Venezuelan tail number YV-3531.

C. Findings

Under the applicable standard set forth in Section 766.24 of the Regulations and my review of the entire record, I find that the evidence presented by BIS convincingly demonstrates that the denied persons have acted in violation of the Regulations and the TDO; that such violations have been significant, deliberate and covert; and that given the foregoing and the nature of the matters

under investigation, there is a likelihood of imminent violations. Therefore, renewal of the TDO is necessary in the public interest to prevent imminent violation of the Regulations and to give notice to companies and individuals in the United States and abroad that they should continue to avoid dealing with Mahan Airways and Al Naser Airlines and the other denied persons, in connection with export and reexport transactions involving items subject to the Regulations and in connection with any other activity subject to the Regulations.

III. Order

It is therefore ordered: First, that MAHAN AIRWAYS, Mahan Tower, No. 21, Azadegan St., M.A. Jenah Exp. Way, Tehran, Iran; PEJMAN MAHMOOD KOSARAYANIFARD A/K/ A KOSARIAN FARD, P.O. Box 52404, Dubai, United Arab Emirates; MAHMOUD AMINI, G#22 Dubai Airport Free Zone, P.O. Box 393754, Dubai, United Arab Emirates, and P.O. Box 52404, Dubai, United Arab Emirates, and Mohamed Abdulla Algaz Building, Al Maktoum Street, Al Rigga, Dubai, United Arab Emirates; KERMAN AVIATION A/K/A GIE KERMAN AVIATION, 42 Avenue Montaigne 75008, Paris, France; SIRJANCO TRADING LLC, P.O. Box 8709, Dubai, United Arab Emirates; MAHAN AIR GENERAL TRADING LLC, 19th Floor Al Moosa Tower One, Sheik Zaved Road, Dubai 40594, United Arab Emirates; MEHDI BAHRAMI, Mahan Airways-Istanbul Office, Cumhuriye Cad. Sibil Apt No: 101 D:6, 34374 Emadad, Sisli Istanbul, Turkey; AL NASER AIRLINES A/K/A AL-NASER AIRLINES A/K/A AL NASER WINGS AIRLINE A/K/A ALNASER AIRLINES AND AIR FREIGHT LTD., Home 46, Al-Karrada, Babil Region, District 929, St 21, Beside Al Jadirya Private Hospital, Baghdad, Iraq, and Al Amirat Street, Section 309. St. 3/H.20, Al Mansour, Baghdad, Iraq, and P.O. Box 28360, Dubai, United Arab Emirates, and P.O. Box 911399, Amman 11191, Jordan; ALI ABDULLAH ALHAY A/K/A ALI ALHAY A/K/A ALI ABDULLAH AHMED ALHAY, Home 46, Al-Karrada, Babil Region, District 929, St 21, Beside Al Jadirya Private Hospital, Baghdad, Iraq, and Anak Street, Qatif, Saudi Arabia 61177; BAHAR SAFWA GENERAL TRADING, P.O. Box 113212, Citadel Tower, Floor-5, Office #504, Business Bay, Dubai, United Arab Emirates, and P.O. Box 8709, Citadel Tower, Business Bay, Dubai, United Arab Emirates; SKY BLUE BIRD GROUP A/K/A SKY BLUE BIRD AVIATION A/K/A SKY BLUE BIRD LTD A/K/A SKY BLUE BIRD FZC,

Arab Emirates and Tehran, Iran. In addition, on November 8, 2021, EP–MMQ (MSN 346) flew on routes between Shenzhen, China and Tehran, Iran.

⁵³ Publicly available flight tracking information shows that on May 2, 2022, EP–MME (MSN 376) flew on routes between Moscow, Russia and Tehran, Iran, and on May 5, 2022, EP–MNO (MSN 595) flew on routes between Damascus, Syria and Tehran, Iran. In addition, on May 6, 2022, EP–MMB (MSN 56) flew on routes between Guangzhou, China and Tehran, Iran.

⁵⁴ https://centreforaviation.com/news/mahan-air-launches-moscow-sheremetyevo-service-1131185.

⁵⁵ The TDO prohibits Mahan from being eligible to use license exception Aircraft, Vessels, and Spacecraft (AVS) (Section 740.15 of the EAR).

⁵⁶ https://home.treasury.gov/system/files/126/20220425_toll.pdf

⁵⁷ https://bis.doc.gov/index.php/documents/ about-bis/newsroom/press-releases/3138-bis-pressrelease-gp10-iranian-craft-additions/file.

⁵⁸ BIS issued a separate TDO denying the export privileges of EMTRASUR for a period of 180 days. See 87 FR 47,964 (Aug. 5, 2022).

⁵⁹On or about February 7, 2020, U.S. Department of the Treasury's Office of Foreign Assets Control ("OFAC") added CONVIASA, a Venezuelan stateowned airline, to the list of Specially Designated Nationals ("SDN") pursuant to Executive Order (E.O.) 13884. See https://home.treasury.gov/news/press-releases/sm903.

P.O. Box 16111, Ras Al Khaimah Trade Zone, United Arab Emirates; and ISSAM SHAMMOUT A/K/A MUHAMMAD ISAM MUHAMMAD ANWAR NUR SHAMMOUT A/K/A ISSAM ANWAR, Philips Building, 4th Floor, Al Fardous Street, Damascus, Syria, and Al Kolaa, Beirut, Lebanon 151515, and 17–18 Margaret Street, 4th Floor, London, W1W 8RP, United Kingdom, and Cumhuriyet Mah. Kavakli San St. Fulya, Cad. Hazar Sok. No.14/A Silivri, Istanbul, Turkey, and when acting for or on their behalf, any successors or assigns, agents, or employees (each a "Denied Person" and collectively the "Denied Persons") may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as "item") exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR including, but not limited to:

A. Applying for, obtaining, or using any license, license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or engaging in any other activity subject to the EAR; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or from any other activity subject to the EAR.

Second, that no person may, directly or indirectly, do any of the following:

A. Export, reexport, or transfer (incountry) to or on behalf of a Denied Person any item subject to the EAR;

B. Take any action that facilitates the acquisition or attempted acquisition by a Denied Person of the ownership, possession, or control of any item subject to the EAR that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby a Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from a Denied Person of any item subject to the EAR that has been exported from the United States;

D. Obtain from a Denied Person in the United States any item subject to the EAR with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the EAR that has been or will be exported from the United States and which is owned, possessed or controlled by a Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by a Denied Person if such service involves the use of any item subject to the EAR that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, that, after notice and opportunity for comment as provided in section 766.23 of the EAR, any other person, firm, corporation, or business organization related to a Denied Person by ownership, control, position of responsibility, affiliation or other connection in the conduct of trade or business may also be made subject to the provisions of this Order.

Fourth, that this Order does not prohibit any export, reexport, or other transaction subject to the EAR where the only items involved that are subject to the EAR are the foreign-produced direct product of U.S.-origin technology.

In accordance with the provisions of Sections 766.24(e) of the EAR, Mahan Airways, Al Naser Airlines, Ali Abdullah Alhay, and/or Bahar Safwa General Trading may, at any time, appeal this Order by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202-4022. In accordance with the provisions of Sections 766.23(c)(2) and 766.24(e)(3) of the EAR, Pejman Mahmood Kosarayanifard, Mahmoud Amini, Kerman Aviation, Sirjanco Trading LLC, Mahan Air General Trading LLC, Mehdi Bahrami, Sky Blue Bird Group, and/or Issam Shammout may, at any time, appeal their inclusion as a related person by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202-4022.

In accordance with the provisions of Section 766.24(d) of the EAR, BIS may seek renewal of this Order by filing a written request not later than 20 days before the expiration date. A renewal request may be opposed by Mahan Airways, Al Naser Airlines, Ali Abdullah Alhay, and/or Bahar Safwa General Trading as provided in Section 766.24(d), by filing a written submission with the Assistant Secretary of Commerce for Export Enforcement, which must be received not later than

seven days before the expiration date of the Order.

A copy of this Order shall be provided to Mahan Airways, Al Naser Airlines, Ali Abdullah Alhay, and Bahar Safwa General Trading and each related person, and shall be published in the Federal Register.

This Order is effective immediately and shall remain in effect for 180 days.

Matthew S. Axelrod,

Assistant Secretary of Commerce for Export Enforcement.

[FR Doc. 2022–24682 Filed 11–10–22; 8:45 am] BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XC550]

Marine Mammals; File No. 26750

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that the Burke Museum, University of Washington, Box 353010, Seattle, WA 98195 (Responsible Party: Gabriela Chavarria, Ph.D.) has applied in due form for a permit to import, export, and receive marine mammal parts for scientific research.

DATES: Written, telefaxed, or email comments must be received on or before December 14, 2022.

ADDRESSES: The application and related documents are available for review by selecting "Records Open for Public Comment" from the "Features" box on the Applications and Permits for Protected Species (APPS) home page, https://apps.nmfs.noaa.gov, and then selecting File No. 26750 from the list of available applications. These documents are also available upon written request via email to NMFS.Pr1Comments@noaa.gov.

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov*. Please include File No. 26750 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to *NMFS.Pr1Comments@* noaa.gov. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Shasta McClenahan, Ph.D., or Jennifer Skidmore, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*).

The applicant proposes to receive, import, and export parts from up to 100 individual cetaceans and 100 individual pinnipeds (excluding walrus), annually. Sources of foreign and domestic parts may include subsistence harvests, captive animals, other authorized researchers or curated collections, bycatch from legal commercial fishing operations, seizures from law enforcement, and foreign stranded animals. Parts would be used for scientific research, curation, and education to support the conservation and management of marine mammal species and marine ecosystems. The permit would be valid for 5 years from the date of issuance.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: November 8, 2022.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–24712 Filed 11–10–22; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XC526]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce. **ACTION:** Notice; public meeting.

SUMMARY: The Ecosystem and Ocean Planning (EOP) Committee and Advisory Panel (AP) of the Mid-Atlantic Fishery Management Council (Council) will hold a joint meeting. See SUPPLEMENTARY INFORMATION for agenda details

DATES: The meeting will be held on Wednesday, November 30, 2022, from 9 a.m. to 12 p.m.

ADDRESSES: The meeting will take place over webinar with a telephone-only connection option. Details on how to connect to the webinar by computer and by telephone will be available at: www.mafmc.org.

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; website: www.mafmc.org.

FOR FURTHER INFORMATION CONTACT:

Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is for the EOP Committee and AP to begin a comprehensive review of the Council's Ecosystem Approach to Fisheries Management (EAFM) risk assessment. The Council completed the initial risk assessment in 2017 to provide a snapshot of the current risks to meeting management objectives and helps the Council decide where to focus resources to address priority ecosystem considerations. This comprehensive review will allow the Council to evaluate new and existing objectives and risk elements and consider new information and analyses that are available to help update the risk assessment. It is anticipated the review will be completed in the fall of 2023.

A detailed agenda and background documents will be made available on the Council's website (www.mafmc.org) prior to the meeting.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to Shelley Spedden, (302) 526–5251, at least 5 days prior to the meeting date.

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

Dated: November 7, 2022.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service. [FR Doc. 2022–24631 Filed 11–10–22; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XC523]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Monkfish 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 hybrid meeting will be held on Tuesday, November 29, 2022, at 10 a.m.

Webinar registration URL information: https://attendee.gotowebinar.com/register/3966218144088598795.

ADDRESSES:

Meeting address: This meeting will be held at the Radisson Airport Hotel, 2081 Post Road, Warwick, RI 02886; telephone: (401) 739–3000.

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 Monkfish Committee will meet to receive a progress update on developing 2023–25 specifications and other management measures (regarding Days-At-Sea, possession limits, and gillnet mesh size). Review the preliminary impact analysis of alternatives and recommend final preferred alternatives to the Council regarding Framework Adjustment 13. The Committee will finalize recommendations to the Council for 2023 Council management priorities regarding monkfish. Other business will be discussed if necessary.

Although non-emergency issues not contained on this agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council 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.

Special Accommodations

This meeting is physically accessible to people with disabilities. This meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request. 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: November 7, 2022.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service. [FR Doc. 2022–24629 Filed 11–10–22; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XC524]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Monkfish Advisory Panel via webinar 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 webinar will be held on Monday, November 28, 2022, at 10 a.m. Webinar registration URL information: https://attendee.gotowebinar.com/register/912769899953262095.

ADDRESSES: 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 Advisory Panel will receive a progress update on developing 2023–25 specifications and other management measures (regarding Days-At-Sea, possession limits, and gillnet mesh size). Review the preliminary impact analysis of alternatives and recommend final preferred alternatives to the Committee regarding Framework Adjustment 13. The panel will finalize recommendations to the Committee for 2023 Council management priorities regarding monkfish. Other business may be discussed, as necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council 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: November 7, 2022.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service. [FR Doc. 2022–24630 Filed 11–10–22; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XC533]

Marine Mammals and Endangered Species

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

ACTION: Notice; issuance of permits, permit amendments, and permit modifications.

SUMMARY: Notice is hereby given that permits, permit amendments, and permit modifications 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 via email to *NMFS.Pr1Comments@noaa.gov.*

FOR FURTHER INFORMATION CONTACT:

Amy Hapeman (Permit Nos. 26268 and 26329), Shasta McClenahan, Ph.D., (No. 21422–01, 25987, 26594, 26596, and 26602), Erin Markin, Ph.D., (Permit Nos. 20528–04 and 25818), Courtney Smith, Ph.D. (Permit Nos. 20648–02 and 26614), and Sara Young (Permit No. 26532); at (301) 427–8401.

SUPPLEMENTARY INFORMATION: Notices were published in the Federal Register on the dates listed below that requests for a permit, permit amendment, or permit modification 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 activities, go to www.federalregister.gov and search on the permit number provided in Table 1 below.

TABLE 1—ISSUED PERMITS, PERMIT AMENDMENTS, AND PERMIT MODIFICATIONS

Permit No.	RTID	Applicant	Previous Federal Register Notice	Issuance date
20528–04	0648-XC354	South Carolina Department of Natural Resources, 217 Fort Johnson Road, Charleston, SC 29412 (Responsible Party: Bill Post).	, , , , , , , , , , , , , , , , , , ,	October 31, 2022.

Permit No.	RTID	Applicant	Previous Federal Register Notice	Issuance date
20648–02	0648-XC126	Heidi Pearson, Ph.D., University of Alaska— Southeast, 11120 Glacier Hwy, AND1, Juneau, AK 99801.	87 FR 41291, July 12, 2022	October 28, 2022.
21422–01	0648-XC100	James Lloyd-Smith, Ph.D., University of California, Los Angeles, 610 Charles E. Young Dr. South, Box 723905, Los Angeles, CA 90095.	82 FR 48985, October 23, 2017	October 24, 2022.
25818	0648-XC238	Paul Jobsis, Ph.D., University of the Virgin Islands, Center for Marine and Environmental Studies, 2 John Brewers Bay, St. Thomas, VI 00802.	87 FR 48157, August 8, 2022	October 25, 2022.
25987	0648-XC239	James Darling, Ph.D., Whale Trust, P.O. Box 384, Tofino, BC V0R2Z0, Canada.	87 FR 47985, August 5, 2022	October 26, 2022.
26268	0648-XC209	Kate Mansfield, Ph.D., University of Central Florida, Biology, 4000 Central Florida Blvd. Bldg 20, Room 301, Orlando, FL 32816.	87 FR 45761, July 29, 2022	October 19, 2022.
26329	0648-XC195	Brandon Southall, Ph.D., Southall Environmental Associates, Inc., 9099 Soquel Drive, Suite 8, Aptos, CA 95076.	87 FR 43501, July 21, 2022	October 21, 2022.
26532	0648-XC279	The Marine Mammal Center, 2000 Bunker Road, Sausalito, CA 94965 (Responsible Party: Dominic Travis).	87 FR 51060, August 19, 2022	October 31, 2022.
26596	0648-XC295	Robin Baird, Ph.D., Cascadia Research Collective, 2181/2 West Fourth Avenue, Olympia, WA 98501.	87 FR 51969, August 24, 2022	October 31, 2022.
26602	0648-XC313	Alison Stimpert, Ph.D., Moss Landing Marine Laboratories, 8272 Moss Landing Rd, Moss Landing, CA 95039.	87 FR 52749, August 29, 2022	October 28, 2022.
26614	0648-XC198	Craig Matkin, North Gulf Oceanic Society, 3430 Main St. Suite B1, Homer, AK 99603.	87 FR 47722, August 4, 2022	October 28, 2022.
26954	0648-XC312	Ann Zoidis, Cetos Research Organization, 51 Kebo Ridge Road, Bar Harbor, ME 04609.	87 FR 52752, August 29, 2022	October 26, 2022.

TABLE 1—ISSUED PERMITS, PERMIT AMENDMENTS, AND PERMIT MODIFICATIONS—Continued

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 FSA

Authority: The requested permits have been issued under the MMPA 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 ESA of 1973, as amended (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 through 226), as applicable.

Dated: November 7, 2022.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–24645 Filed 11–10–22; 8:45 am] BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XC535]

Marine Fisheries Advisory Committee Meeting

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

ACTION: Notice of open public meeting.

SUMMARY: This notice sets forth the proposed schedule and agenda of a forthcoming meeting of the Marine Fisheries Advisory Committee (MAFAC). The members will discuss and provide advice on issues outlined under **SUPPLEMENTARY INFORMATION** below.

DATES: The meeting will be November 29 and 30, 2022, from 8:30 a.m. to 5

p.m., and December 1, from 8:30 a.m. to 4 p.m. Eastern Time.

ADDRESSES: The meeting will be held at the DoubleTree Silver Spring DC North, 8777 Georgia Avenue, Silver Spring, MD 20910; 301–589–0800. Meeting will also be by webinar and teleconference.

FOR FURTHER INFORMATION CONTACT:

Heidi Lovett, MAFAC Assistant Director; 301–427–8034; email: *Heidi.Lovett@noaa.gov.*

SUPPLEMENTARY INFORMATION: As required by section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. 2, notice is hereby given of a meeting of MAFAC. The MAFAC was established by the Secretary of Commerce (Secretary), and, since 1971, advises the Secretary on all living marine resource matters that are the responsibility of the Department of Commerce. The complete charter and summaries of prior meetings are located online at http://www.nmfs.noaa.gov/ocs/mafac/.

Matters To Be Considered

This meeting time and agenda are subject to change.

The meeting is convened to hear presentations and discuss policies and guidance on the following topics: the new NOAA aquaculture strategic plan,

program updates, and seafood communications efforts; fisheries science and the Climate, Ecosystems, and Fisheries Initiative; budget outlook; an overview of habitat restoration funding opportunities; and updates on America the Beautiful and the draft NOAA Fisheries Equity and Environmental Justice Strategy. MAFAC will deliberate on draft reports from subcommittees working on fisheries and seafood industry workforce development and recommendations to update the NOAA Fisheries National Saltwater Recreational Fisheries Policy. MAFAC will discuss various administrative and organizational matters, and meetings of subcommittees and working groups will be convened.

Time and Date

The meeting will be November 29 and 30, 2022, from 8:30 a.m. to 5 p.m., and December 1, from 8:30 a.m. to 4 p.m. Eastern Time, and will be accessible by webinar and teleconference. Access information for the public will be posted at https://www.fisheries.noaa.gov/national/partners/marine-fisheries-advisory-committee-meeting-materials-and-summaries by November 18, 2022.

Dated: November 8, 2022.

Jennifer Lukens,

Director for the Office of Policy, National Marine Fisheries Service.

[FR Doc. 2022–24699 Filed 11–10–22; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XC547]

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of web conference.

SUMMARY: The North Pacific Fishery Management Council (Council) Salmon Bycatch Committee will meet November 28, 2022.

DATES: The meeting will be held on Wednesday, November 28, 2022, from 9 a.m. to 3 p.m., Alaska Time.

ADDRESSES: The meeting will be a web conference. Join online through the link at https://meetings.npfmc.org/Meeting/Details/2965.

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave., Anchorage, AK 99501–2252; telephone: (907) 271–2809. Instructions for attending the meeting are given under SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT: Dr. Diana Stram, Council staff; phone: (907) 271–2809 and email: diana.stram@noaa.gov. For technical support, please contact our administrative staff; email: npfmc.admin@noaa.gov.

SUPPLEMENTARY INFORMATION:

Agenda

Monday, November 28, 2022

The agenda will include: (a) introductions; (b) review draft Terms of Reference; (c) review and provide recommendations on the Chum Salmon Bycatch discussion paper; (d) review State of Alaska Taskforce recommendations (T); and (e) and other business. The agenda is subject to change, and the latest version will be posted at https://meetings.npfmc.org/Meeting/Details/2965 prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone; or by phone only. Connection information will be posted online at: https://meetings.npfmc.org/Meeting/Details/2965.

Public Comment

Public comment letters will be accepted and should be submitted electronically to https://meetings.npfmc.org/Meeting/Details/2965.

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

Dated: November 8, 2022.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service. [FR Doc. 2022–24724 Filed 11–10–22; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XC552]

Western Pacific Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Western Pacific Fishery Management Council (Council) will hold its 146th Scientific and Statistical Committee (SSC), Hawaii Archipelago &

Pacific Remote Island Areas (PRIA) Standing Committee, Executive and Budget Standing Committee, and 193rd Council meetings to take actions on fishery management issues in the Western Pacific Region.

DATES: The meetings will be held between November 29 and December 8, 2022. For specific times and agendas, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The SSC meeting will be held by web conference via Webex. The Standing Committee meetings will be held in a hybrid format with in-person and remote participation (Webex) options available for the members, and public attendance limited to web conference via Webex. In-person attendance for Standing Committee members will be hosted at the Council office, 1164 Bishop Street, Suite 1400, Honolulu, HI 96813.

The 193rd Council Meeting will be held as a hybrid meeting for Council members and public. The in-person portion of the Council Meeting will be held at the Pagoda Hotel, 1525 Rycroft St., Honolulu, HI 96814. Remote participation option will be available via Webex.

Specific information on joining the meeting, connecting to the web conference and providing oral public comments will be posted on the Council website at www.wpcouncil.org. For assistance with the web conference connection, contact the Council office at (808) 522–8220.

Council address: Western Pacific Fishery Management Council, 1164 Bishop Street, Suite 1400, Honolulu, HI 96813.

FOR FURTHER INFORMATION CONTACT:

Kitty M. Simonds, Executive Director, Western Pacific Fishery Management Council; phone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: All times shown are in Hawaii Standard Time. The 146th SSC meeting will be held between 11 a.m. and 5 p.m. on November 29-30, 2022. The Hawaii Archipelago & PRIA Standing Committee will be held between 8 a.m. and 9:30 a.m. on December 5, 2022. The Executive and Budget Standing Committee meeting will be held between 10 a.m. and 11:30 a.m. on December 5, 2022. The portion of the Executive and Budget Standing Committee from 11 a.m. to 11:30 a.m. will be closed to the public for a briefing on litigation in accordance with section 302(i)(3) of the Magnuson-Stevens Fishery Conservation and Management Act (MSA). The 193rd Council meeting will be held between 1:30 p.m. to 5 p.m. on December 5, 2022, 9 a.m. and 5 p.m.

on December 6-7, 2022, and 9 a.m. and 12 p.m. on December 8, 2022.

Please note that the evolving public health situation regarding COVID-19 may affect the conduct of the December Council and its associated meetings. At the time this notice was submitted for publication, the Council anticipated convening the Standing Committee meetings as a hybrid format for members and by web conference for public attendance, and the Council meeting as an in-person meeting with a web conference attendance option. If public participation options will be modified, the Council will post notice on its website at www.wpcouncil.org by, to the extent practicable, 5 calendar

days before each meeting.
Agenda items noted as "Final Action" refer to actions that may result in Council transmittal of a proposed fishery management plan, proposed plan amendment, or proposed regulations to the U.S. Secretary of Commerce, under Sections 304 or 305 of the MSA. In addition to the agenda items listed here, the Council and its advisory bodies will hear recommendations from Council advisors. An opportunity to submit public comment will be provided throughout the agendas. The order in which agenda items are addressed may change and will be announced in advance at the Council meeting. The meetings will run as late as necessary to complete scheduled business.

Background documents for the 193rd Council meeting will be available at www.wpcouncil.org. Written public comments on final action items at the 193rd Council meeting should be received at the Council office by 5 p.m. HST, December 2, 2022, and should be sent to Kitty M. Simonds, Executive Director; Western Pacific Fishery Management Council, 1164 Bishop Street, Suite 1400, Honolulu, HI 96813, phone: (808) 522-8220 or fax: (808) 522-8226; or email: info@wpcouncil.org. Written public comments on all other agenda items may be submitted for the record by email throughout the duration of the meeting. Instructions for providing oral public comments during the meeting will be posted on the Council website. This meeting will be recorded (audio only) for the purposes of generating the minutes of the meeting.

Agenda for the 146th SSC Meeting

Tuesday, November 29, 2022, 11 a.m. to 5 p.m.

- 1. Introductions
- 2. Approval of Draft Agenda and Assignment of Rapporteurs

- 3. Status of the 145th SSC Meeting Recommendations
- 4. Pacific Islands Fisheries Science Center Director Report
- 5. Program Planning and Research A. Alternatives for Fishing Regulations for the Monument Expansion (MEA) in the Northwestern Hawaiian Islands
 - B. Report of the Ecosystem-based Fisheries Management Workshop
 - C. Filling Gaps in Data for Priority Coral Reef Species-Nenue Biosampling in Hawaii
 - D. Review of Paper Inferring Spillover Benefits of the Papahanaumokuakea Marine National Monument
 - E. CCC Area-Based Management Subcommittee Report
 - F. National Standard 1 (NS1) Subgroup on Biomass Proxies Draft Report
 - G. American Samoa Bottomfish Management Unit Species (BMUS) Stock Assessment Western Pacific Stock Assessment Review (WPSAR) Terms of Reference
 - H. Public Comment
- I. SSC Discussion and Recommendations
- 6. Protected Species
- A. False Killer Whale Take Reduction Team Meeting Report
- B. Cross-taxa Impacts of Longline Management Measures
- C. Endangered Species Act (ESA) Section 7 Consultations
 - 1. Final Supplemental Biological Opinions for the Hawaii Deep-set and American Samoa Longline Fishery Draft Biological Opinions
 - 2. Status of the Full Hawaii Deep-set and American Samoa Longline Fishery Draft Biological Opinions
 - D. Public Comment
 - E. SSC Discussion and Recommendations

Wednesday, November 30, 2022, 11 a.m. to 5 p.m.

- 7. Other Business
- A. March 2023 SSC Meetings Dates
- 8. Summary of SSC Recommendations to the Council

Agenda for the Hawaii Archipelago & **PRIA Standing Committee**

Monday, December 5, 2022, 8 a.m. and

- 1. Fisheries Management Measures in the NWHI MEA
 - a. Report of public meetings
 - b. Alternatives for Monument Expansion Fishing Regulations
- 2. North Pacific Striped Marlin Catch Limits
- 3. Advisory Group Reports and Recommendations

- 4. Other Business
- 5. Public Comment
- 6. Discussion and Recommendations

Agenda for the Executive and Budget **Standing Committee**

Monday, December 5, 2022, 10 a.m. and 11:30 a.m. (11 a.m. to 11:30 a.m. CLOSED)

- 1. Financial Reports
- 2. Administrative Reports
- 3. Council Program Plan Report
- 4. October 2022 Council Coordination Committee Meeting Report
- 5. Council Family Changes
- 6. Meetings and Workshops
- 7. Other Issues
- 8. Public Comment
- 9. Discussion and Recommendations
- 10. Briefing on Litigation (Closed Session—pursuant to MSA section 302(i)(3))

Agenda for the 193rd Council Meeting

Monday, December 5, 2022, 1:30 p.m. to 5 p.m.

- 1. Welcome and Introductions
- 2. Approval of the 193rd Council Meeting Agenda
- 3. Approval of the 192nd Council **Meeting Minutes**
- 4. Executive Director's Report
- 5. Agency Reports
 - A. National Marine Fisheries Service
 - 1. Pacific Islands Regional Office
 - 2. Pacific Islands Fisheries Science Center
 - B. NOAA Office of General Counsel Pacific Islands Section
 - C. Enforcement
 - 1. U.S. Coast Guard
 - 2. NOAA Office of Law Enforcement
 - 3. NOAA Office of General Counsel **Enforcement Section** D. U.S. State Department

 - E. U.S. Fish and Wildlife Service
 - F. Public Comment
 - G. Council Discussion and Action

Tuesday, December 6, 2022, 9 a.m. to 5

- 6. Hawaii Archipelago & PRIA
 - A. Moku Pepa
 - B. Department of Land and Natural Resources/Division of Aquatic Resources Report (Legislation, Enforcement)
 - C. Office of Hawaiian Affairs Ocean
 - D. Review of Paper Inferring Spillover Benefits of the Papahanaumokuakea Marine National Monument
 - E. NWHI MEA Fishing Regulations
 - 1. Report of Public Meetings
 - 2. Alternatives for Fishing Regulations for the MEA in the NWHI (Final Action)
 - F. Advisory Group Report and

- Recommendations
- 1. Advisory Panel
- 2. Scientific & Statistical Committee
- 3. Hawaii Archipelago & PRIA Standing Committee
- G. Public Comment
- H. Council Discussion and Action
- 7. Mariana Archipelago
 - A. Guam
 - Department of Agriculture/Division of Aquatic and Wildlife Resources Report
 - 2. Isla Informe
 - B. Commonwealth of the Northern Mariana Islands
 - 1. Arongol Falú
 - Department of Land and Natural Resources/Division of Fish and Wildlife Report
 - C. Advisory Group Report and Recommendations
 - 1. Scientific & Statistical Committee
 - D. Public Comment
 - E. Council Discussion and Action
- 8. Program Planning and Research
 - A. National Legislative Report
 - B. Alternatives for an Aquaculture Management Framework in the Western Pacific (Final Action)
 - C. Report of the Regional Ecosystem-Based Fishery Management Workshop
 - D. Report of the Council Coordination Committee Area-based Management Subcommittee
 - E. Territory BMUS Revision Working Group Reports
 - F. Regional Communications & Outreach Report
 - G. Advisory Group Report and Recommendations
 - 1. Scientific & Statistical Committee
 - H. Public Comment
 - I. Council Discussion and Action

Tuesday, December 6, 2022, 4:30 p.m. to 5 p.m.

Public Comment on Non-Agenda Items

Wednesday, December 7, 2022, 9 a.m. to 5 p.m.

- 9. Protected Species
 - A. Review of Cross-taxa Impacts of Longline Management Measures
 - B. False Killer Whale Take Reduction Team Meeting Report
 - C. ESA Section 7 Consultations
 - Final Supplemental Biological Opinions for the Hawaii Deep-set and American Samoa Longline Fishery Draft Biological Opinions
 - Status of the Full Hawaii Deep-set and American Samoa Longline Fishery Draft Biological Opinions
 - D. ESA and Marine Mammal Protection Act Updates
 - E. Advisory Group Report and Recommendations
 - 1. Advisory Panel

- 2. Scientific & Statistical Committee
- F. Public Comment
- G. Council Discussion and Action
- 10. Pelagic & International Fisheries
 - A. North Pacific Striped Marlin Catch Limits (Final Action)
 - B. Electronic Monitoring: Best Practices for Implementation and Options for the Western Pacific Region
 - C. International Fisheries Issues
 - 1. Western and Central Pacific Ocean Longline Management Workshop
 - 2. Outcomes of 19th Regular Session of the Western and Central Pacific Fisheries Commission
 - D. Advisory Group Report and Recommendations
 - 1. Advisory Panel
 - 2. Scientific & Statistical Committee
 - 3. Hawaiʻi Archipelago & PRIA Standing Committee
 - E. Public Comment
 - F. Council Discussion and Action

Thursday, December 8, 2022, 9 a.m. to 12 p.m.

- 11. American Samoa Archipelago
 - A. Motu Lipoti
 - B. Department of Marine and Wildlife Resources Report
 - C. WPSAR Terms of Reference for American Samoa Bottomfish Stock Assessment
 - D. Advisory Group Report and Recommendations
 - 1. Scientific & Statistical Committee
 - E. Public Comment
 - F. Council Discussion and Action
- 12. Administrative Matters
 - A. Financial Reports
 - B. Administrative Reports
 - C. Ethics Training
 - D. Council Program Planning Report
 - E. October 2022 Council Coordination Committee Meeting Report
 - F. Council Family Changes
 - G. Meetings and Workshops
 - H. Standing Committee Reports
 - 1. Executive and Budget Standing Committee
 - I. Public Comment
 - J. Council Discussion and Action
- 13. Other Business
 - A. Election of Officers

Non-emergency issues not contained in this agenda may come before the Council for discussion and formal Council action during its 193rd meeting. However, Council action on regulatory issues will be restricted to those issues specifically listed in this document and any regulatory issue arising after publication of this document that requires emergency action under section 305(c) of the MSA, provided the public has been notified of the Council's intent to take action to address the emergency.

Special Accommodations

These meetings are accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

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

Dated: November 8, 2022.

Rev Israel Marquez,

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

[FR Doc. 2022–24725 Filed 11–10–22; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XC531]

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery
Management Council (Pacific Council)
will convene a one-day webinar meeting
of its Groundfish Management Team
(GMT) to discuss outcomes of the
November Pacific Council meeting and
to initiate discussions and analyses on
groundfish items on the Pacific
Council's March and April 2023
agendas. This meeting is open to the
public.

DATES: The online meeting will be held on Monday, November 28, 2022, starting at 9 a.m. Pacific time and ending at 5 p.m. Pacific time, or when business has been completed for the day.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see www.pcouncil.org). You may send an email to Mr. Kris Kleinschmidt (kris.kleinschmidt@noaa.gov) or contact him at (503) 820—2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT:

Todd Phillips, Staff Officer, Pacific Council; telephone: (503) 820–2426.

SUPPLEMENTARY INFORMATION: The primary purpose of the GMT webinar is

to discuss outcomes of the November Pacific Council meeting and to initiate discussions and analyses on groundfish items, such as stock definitions, on the Pacific Council's March and April 2023 agendas necessary to inform their overwinter analytical work. The GMT may also address other Council assignments relating to groundfish management. No management actions will be decided by the GMT. A detailed agenda for the webinar will be available on the Pacific Council's website prior to the meeting.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (kris.kleinschmidt@noaa.gov; (503) 820–2412) at least 10 days prior to the meeting date.

Dated: November 7, 2022.

Rey Israel Marquez,

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

[FR Doc. 2022–24632 Filed 11–10–22; 8:45 am]

BILLING CODE 3510-22-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed deletions from the Procurement List.

SUMMARY: The Committee is proposing to delete services from to the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilitiess.

DATES: Comments must be received on or before: December 14, 2022.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Washington, DC 20024. **FOR FURTHER INFORMATION CONTACT:** For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov*.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

The following service(s) are proposed for deletion from the Procurement List:

Service(s)

Service Type: Administrative Services Mandatory for: Charlie Norwood VA Medical Center, Augusta, GA

Designated Source of Supply: Bobby Dodd Institute, Inc., Atlanta, GA

Contracting Activity: VETERANS AFFAIRS, DEPARTMENT OF, 247–NETWORK CONTRACT OFFICE 7

Service Type: Administrative Services
Mandatory for: Department of Veterans
Affairs, Carl Vinson VA Medical Center,
Dublin, GA, 1826 Veterans Blvd., Dublin,
GA

Designated Source of Supply: Bobby Dodd Institute, Inc., Atlanta, GA Contracting Activity: VETERANS AFFAIRS, DEPARTMENT OF, 247–NETWORK

CONTRACT OFFICE 7

Service Type: Document Assembly Mandatory for: USDA Forest Service, Northern Research Station, Saint Paul, MN, 1992 Folwell Avenue, Saint Paul, MN

Designated Source of Supply: AccessAbility, Inc., Minneapolis, MN

Contracting Activity: FOREST SERVICE, USDA FOREST SERVICE

Service Type: Custodial & Pest Control Services

Mandatory for: US Navy, Naval Operations Support Center, Wilmington, NC, 3623 Carolina Beach Rd., Wilmington, NC

Mandatory Source of Supply: OE Enterprises, Inc., Hillsborough, NC

Contracting Activity: DEPT OF THE NAVY, NAVAL FAC ENGINEERING CMD MID LANT

Michael R. Jurkowski,

Acting Director, Business Operations.
[FR Doc. 2022–24657 Filed 11–10–22; 8:45 am]
BILLING CODE 6353–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Comment Request; Application Package for Day of Service Application Instructions (MLK + 9/11)

AGENCY: The Corporation for National and Community Service.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Corporation for National and Community Service (operating as AmeriCorps) is proposing to renew an information collection.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by January 13, 2023.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

- (1) Electronically through www.regulations.gov (preferred method).
- (2) By mail sent to: AmeriCorps, Attention Sharron Tendai, 250 E Street SW, Washington, DC 20525.
- (3) By hand delivery or by courier to the AmeriCorps mailroom at the mail address given in paragraph (2) above, between 9 a.m. and 4 p.m. Eastern Time, Monday through Friday, except Federal holidays.

Comments submitted in response to this notice may be made available to the public through regulations.gov. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comment that may be made available to the public, notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Sharron Tendai, 202–606–3904, or by

Sharron Tendai, 202–606–3904, or by email at *stendai@cns.gov*.

SUPPLEMENTARY INFORMATION:

Title of Collection: Day of Service Application Instructions (MLK + 9/11). OMB Control Number: 3045–0180. Type of Review: Renewal. Respondents/Affected Public: Organizations.

Total Estimated Number of Annual Responses: 70.

Total Estimated Number of Annual Burden Hours: 1,400.

Abstract: This information collection seeks feedback on AmeriCorps Day of Service Application Instructions for future MLK and 9/11 Day of Service grant competitions after the expiration of the current Application Instructions. AmeriCorps also seeks to continue using the currently approved information collection until the revised information collection is approved by OMB. The currently approved information collection is due to expire on January 31, 2023.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. All written comments will be available for public inspection on regulations.gov.

Margery Ansara,

Acting Chief of Program Operations. [FR Doc. 2022–24644 Filed 11–10–22; 8:45 am]

BILLING CODE 6050-28-P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Comment Request; Application Package for Disability Accommodation Reimbursement Request Form

AGENCY: The Corporation for National and Community Service.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Corporation for National and Community Service (operating as AmeriCorps) is proposing to renew an information collection.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by January 13, 2023.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

- (1) Electronically through www.regulations.gov (preferred method).
- (2) By mail sent to: AmeriCorps, Attention Sharron Tendai, 250 E Street SW, Washington, DC 20525.
- (3) By hand delivery or by courier to the AmeriCorps mailroom at the mail address given in paragraph (2) above, between 9 a.m. and 4 p.m. eastern time, Monday through Friday, except Federal holidays.

Comments submitted in response to this notice may be made available to the public through regulations.gov. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comment that may be made available to the public, notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT:

Sharron Tendai, 202–606–3904, or by email at *stendai@cns.gov*.

SUPPLEMENTARY INFORMATION:

Title of Collection: Disability Accommodation Reimbursement Request Form.

OMB Control Number: 3045–0179.
Type of Review: Renewal.
Respondents/Affected Public:
Individuals, businesses, organizations,
State, local and Tribal governments.

Total Estimated Number of Annual Responses: 20.

Total Estimated Number of Annual Burden Hours: 20 minutes.

Abstract: AmeriCorps grantees provide the information to request reimbursement for services associated with reasonable accommodation of AmeriCorps service members. The information will be collected electronically via email by submission of this form and the receipt(s) for services. AmeriCorps also seeks to continue using the currently approved information collection until the revised information collection is approved by OMB. The currently approved information collection is due to expire on January 31, 2023.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. All written comments will be available for public inspection on regulations.gov.

Margery Ansara,

Acting Chief of Program Operations.
[FR Doc. 2022–24639 Filed 11–10–22; 8:45 am]

BILLING CODE 6050-28-P

DEPARTMENT OF DEFENSE

Office of the Secretary [Docket ID DoD-2022-OS-0123]

Privacy Act of 1974; System of Records

AGENCY: Defense Media Activity (DMA), Department of Defense (DoD).

ACTION: Notice of a new system of

records.

SUMMARY: In accordance with the Privacy Act of 1974, the DMA is establishing a new system of records titled, "Defense Visual Information Distribution Service (DVIDS)," DPA-04. The system collects, ingests, stores, transmits, and organizes public affairs released DoD media in various content types. It improves data quality, automation, and linking of defense visual information across DoD for mission readiness and visual information records management.

DATES: This system of records is effective upon publication; however, comments on the Routine Uses will be accepted on or before December 14, 2022. The Routine Uses are effective at the close of the comment period.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

*Federal Rulemaking Portal: https://www.regulations.gov.

Follow the instructions for submitting comments.

*Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Mailbox #24 Suite 08D09, Alexandria, VA 22350– 1700.

Instructions: All submissions received must include the agency name and docket number 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 https://www.regulations.gov as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Gail Jones, Defense Media Activity, Privacy Officer, 6700 Taylor Avenue, Fort Meade, MD 20755–2253, or by phone at (301) 222–6040.

SUPPLEMENTARY INFORMATION:

I. Background

The DVIDS system of record is a stateof-the-art, 24/7 operation owned by

DMA that provides timely, accurate and reliable connection between the media around the world and the military serving at home and abroad. DVIDS supports media organizations to access U.S. service members and commanders deployed in support of military operations worldwide. The system enables media outlets to receive immediate, first-hand information and interviews with commanders and subject matter experts directly involved with fast-breaking news. The DVIDS System is the system that holds the DoD archive that is then submitted to the National Archives. The DVIDS is authorized under DoDD 5105.74, "Defense Media Activity," and DoDI 5040.02, "Visual Information." The information collected in the process of a media request or registration form is not shared with any outside private organizations and is shared with other Government agencies if it is necessary to respond to the inquiry or otherwise by law. The information collected is used to validate registered users and DoD approved media content submitters as well as to deliver routine requested content or information.

DoD SORNs have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or at the Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency (OATSD(PCLT)) website at https://dpcld.defense.gov/privacy.

II. Privacy Act

Under the Privacy Act, a "system of records" is a group of records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined as a U.S. citizen or lawful permanent resident.

In accordance with 5 U.S.C. 552a(r) and Office of Management and Budget (OMB) Circular No. A–108, OATSD(PCLT) has provided a report of this system of records to the OMB and to Congress.

Dated: November 7, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

SYSTEM NAME AND NUMBER:

Defense Visual Information Distribution Service (DVIDS), DPA 04.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

3845 Pleasantdale Road, Atlanta, GA 30340–4205.

SYSTEM MANAGER(S):

Defense Media Activity (DMA) DVIDS Program Manager, 3845 Pleasantdale Road Atlanta, GA 30340–4205, (678) 421–6776.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 113, Secretary of Defense; DoDI 5105.74, Defense Media Activity; and DoDI 5040.02, Visual Information.

PURPOSE(S) OF THE SYSTEM:

The DVIDS:

A. Serves as an enterprise shared services for collecting, storing, and distributing visual information and public affairs information to the internal DoD audience.

B. Serves as an enterprise shared service for distribution to the media and public.

C. Improves data quality, automation, and linking of defense visual information across DoD for mission readiness and visual information records management.

D. Executes the DoD Joint Hometown News (JHN) program which provides leaders, managers and service members a capability to release news about service members' accomplishments to their hometown media entities.

E. Provides a shared service to comply with program requirements, and applicable laws and regulations to preserve and maintain confidentiality of the registered users and DoD approved media content submitters personally identifiable information (PII).

F. Serves as the official system for the Visual Information Records Center Mission to Archive DoD content and transfer it to the National Archives in accordance with 44 U.S.C 3103, Transfer of records to records centers.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

General public and Federal and contractor personnel from the DoD and other federal agencies receiving DVIDS services from the DMA. This includes DoD civilian and contractor personnel performing DVIDS oversight duties; military, civilian, and contractor personnel from the DoD and other federal agencies. Also, journalists who produce content available on DVIDS.

CATEGORIES OF RECORDS IN THE SYSTEM:

A. Non Government Registered users: Name; personal and work telephone numbers; personal and work email.

B. DoD Public Affairs, Visual Information, and Combat Camera approved media content submitters: Name; personal and work telephone numbers; personal and work email; position/title; grade/rank, and branch.

C. Attribution of Publicly Released Media Content such as images, video, news, audio, graphics, publications, podcasts and webcasts to the journalist (searchable by journalist's name in order to see all media content associated to a specific journalist).

Note: All content is approved and released by the DoD Public Affairs Officer prior to publication to the DVIDS website.

RECORD SOURCE CATEGORIES:

Information is obtained from the individual either in email, or web form online and then entered into DVIDS, or via direct entry electronically into DVIDS.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a (b) of the Privacy Act of 1974, as amended, the records contained herein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552(b)(1) as follows:

A. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal Government when necessary to accomplish an agency function related to this system of records.

B. To the appropriate Federal, State, local, territorial, tribal, foreign, or international law enforcement authority or other appropriate entity where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law, whether criminal, civil, or regulatory in nature.

C. To any component of the Department of Justice for the purpose of representing the DoD, or its components, officers, employees, or members in pending or potential litigation to which the record is pertinent.

D. In an appropriate proceeding before a court, grand jury, or administrative or adjudicative body or official, when the DoD or other Agency representing the DoD determines the records are relevant and necessary to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

E. To the National Archives and Records Administration for the purpose of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

F. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

G. To appropriate agencies, entities, and persons when (1) the DoD suspects or confirms a breach of the System of Records; (2) the DoD determined as a result of the suspected or confirmed breach there is a risk of harm to individuals, the DoD (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the DoD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

H. To another Federal agency or Federal entity, when the DoD determines information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

I. To another Federal, State or local agency for the purpose of comparing to the agency's system of records or to non-Federal records, in coordination with an Office of Inspector General in conducting an audit, investigation, inspection, evaluation, or some other review as authorized by the Inspector General Act of 1987, as amended.

J. To such recipients and under such circumstances and procedures as are mandated by Federal statute or treaty.

K. To appropriate Federal, State, local, territorial, tribal, foreign, or international agencies for the purpose of counterintelligence activities authorized by U.S. law or Executive Order, or for the purpose of executing or enforcing laws designed to protect the national security or homeland security of the United States, including those relating to the sharing of records or information concerning terrorism, homeland security, or law enforcement.

L. To the news media and the public unless it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Electronic storage media. Electronic records may be stored in agency-owned cloud environments; or in vendor Cloud Service Offerings certified under the Federal Risk and Authorization Management Program (FedRAMP).

POLICIES AND PRACTICES FOR RETRIEVAL OF **RECORDS:**

Records may be retrieved by name.

POLICIES AND PRACTICES FOR RETENTION AND **DISPOSAL OF RECORDS:**

Temporary. Cut off after system is superseded by a new iteration, or is terminated, defunded, or when no longer needed for administrative, legal, audit, or other operational purposes. Destroy 5 years after cutoff.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL **SAFEGUARDS:**

Administrative: backups are secured off-site, encryption of backups, methods to ensure only authorized personnel have access to PII, periodic security audits, and regular monitoring of users' security practices. Physical: cipher locks, closed circuit TV, key cards, and security guards. Technical safeguards: Common Access Card, DoD public key infrastructure certificates, encryption of data at rest, encryption of data in transit, firewall, intrusion detection system, and role-based access control, used only for privileged (elevated roles).

RECORD ACCESS PROCEDURES:

Individuals seeking access to their records should address written requests to the Office of the Secretary of Defense/ Joint Staff Freedom of Information Act Requester Service Center, 1155 Defense Pentagon, Washington, DC 20301-1155. For verification purposes, individuals should provide full name, current address, and sufficient details to permit locating pertinent records, and signature. Signed, written requests should contain the individual's full name, telephone number, street address, email address, and name and number of this system of records notice. In addition, the requester must provide either a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

If executed outside the United States: "I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).

If executed within the United States, its territories, possessions, or commonwealths: "I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature)."

CONTESTING RECORD PROCEDURES:

The DoD rules for accessing records, contesting contents, and appealing initial agency determinations are published in 32 CFR part 310, or may be obtained from the system manger.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether information about themselves is contained in this system of records should follow the instructions for Record Access Procedures above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None

HISTORY:

N/A

[FR Doc. 2022–24646 Filed 11–10–22; 8:45 am]

DEPARTMENT OF DEFENSE

Office of the Secretary

Department of Defense Wage Committee (DoDWC); Notice of Federal Advisory Committee Meetings

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Notice of closed Federal Advisory Committee meetings.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meetings of the DoDWC will take place.

DATES:

Tuesday, November 15, 2022 from 10:00 a.m. to 1:00 p.m. and will be closed to the public.

Tuesday, November 29, 2022 from 10:00 a.m. to 11:00 a.m. and will be closed to the public.

Tuesday, December 13, 2022 from 10:00 a.m. to 12:30 p.m. and will be closed to the public.

Tuesday, December 27, 2022 from 10:00 a.m. to 10:30 a.m. and will be closed to the public.

Tuesday, January 10, 2023 from 10:00 a.m. to 12:00 p.m. and will be closed to the public.

Tuesday, January 24, 2023 from 10:00 a.m. to 10:30 a.m. and will be closed to the public.

Tuesday, February 7, 2023 from 10:00 a.m. to 12:30 p.m. and will be closed to the public.

ADDRESSES: The closed meetings will be held by teleconference.

FOR FURTHER INFORMATION CONTACT:

Mr. Karl Fendt, (571) 372-1618 (voice),

karl.h.fendt.civ@mail.mil (email), 4800 Mark Center Drive, Suite 05G21, Alexandria, Virginia 22350 (mailing address). Any agenda updates can be found at the DoDWC's official website: https://wageandsalary.dcpas.osd.mil/BWN/DODWC/.

SUPPLEMENTARY INFORMATION: Due to circumstances beyond the control of the Department of Defense and the Designated Federal Officer for the DoDWC, the DoDWC was unable to provide public notification required by 41 CFR 102–3.450 (a) concerning its November 15, 2022 meeting. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

These meetings are being held under the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C. Appendix), the Government in the Sunshine Act (5 U.S.C. 552b), and 41 CFR 102–3.140 and 102–3.150.

Purpose of the Meeting: The purpose of these meetings is to provide independent advice and recommendations on matters relating to the conduct of wage surveys and the establishment of wage schedules for all appropriated fund and non-appropriated fund areas of blue-collar employees within the Department of Defense.

Agendas

November 15, 2022

Opening Remarks by Chair and Designated Federal Officer (DFO).

Reviewing survey results and/or survey specifications for the following Appropriated Fund areas:

- 1. Any items needing further clarification or action from the previous agenda.
- 2. Wage Schedule (Full Scale) for the Los Angeles, California wage area (AC–013).
- 3. Wage Schedule (Full Scale) for the San Bernardino-Riverside-Ontario, California wage area (AC-016).
- 4. Wage Schedule (Full Scale) for the Santa Barbara, California wage area (AC–019).
- 5. Wage Schedule (Full Scale) for the New London, Connecticut wage area (AC–025).
- 6. Wage Schedule (Full Scale) for the Panama City, Florida wage area (AC–033).
- 7. Wage Schedule (Full Scale) for the Chicago, Illinois wage area (AC–047).
- 8. Wage Schedule (Full Scale) for the Las Vegas, Nevada wage area (AC-085).
- 9. Wage Schedule (Full Scale) for the Portsmouth, New Hampshire wage area (AC–087).

- 10. Wage Schedule (Full Scale) for the Seattle-Everett-Tacoma, Washington wage area (AC-143).
- 11. Wage Schedule (Wage Change) for the San Diego, California wage area (AC-017).
- 12. Wage Schedule (Wage Change) for the San Francisco, California wage area (AC–018).
- 13. Wage Schedule (Wage Change) for the Pensacola, Florida wage area (AC– 034).
- 14. Wage Schedule (Wage Change) for the Central Illinois wage area (AC-046).
- 15. Wage Schedule (Wage Change) for the Des Moines, Iowa wage area (AC–054).
- 16. Wage Schedule (Wage Change) for the Baltimore, Maryland wage area (AC–066)
- 17. Wage Schedule (Wage Change) for the Buffalo, New York wage area (AC–
- 18. Survey Specifications for the Sacramento, California wage area (AC–014).
- 19. Survey Specifications for the Stockton, California wage area (AC–020).
- 20. Survey Specifications for the Miami, Florida wage area (AC-031).
- 21. Survey Specifications for the Jackson, Mississippi wage area (AC–078)
- 22. Survey Specifications for the Meridian, Mississippi wage area (AC–079)
- 23. Survey Specifications for the Cincinnati, Ohio wage area (AC–104).
- 24. Survey Specifications for the Eastern Tennessee wage area (AC–123).
- 25. Special Pay—Southwest Power Rate
- 26. Special Pay—North Central Power Rate
- 27. Special Pay—Los Angeles, California Special Rates
- 28. Special Pay—New London, Connecticut Special Rates
- 29. Special Pay—San Diego, California Special Rates
- 30. Any items needing further clarification from this agenda may be discussed during future scheduled meetings.

Closing Remarks by Chair.

November 29, 2022:

Opening Remarks by Chair and DFO. Reviewing survey results and/or survey specifications for the following Nonappropriated Fund areas:

- 1. Any items needing further clarification or action from the previous agenda.
- 2. Wage Schedule (Full Scale) for the Maricopa, Arizona wage area (AC–012).
- 3. Wage Schedule (Full Scale) for the Pima, Arizona wage area (AC-013).

- 4. Wage Schedule (Full Scale) for the Yuma, Arizona wage area (AC–055).
- 5. Wage Schedule (Full Scale) for the Kings-Queens, New York wage area (AC–091).
- 6. Wage Schedule (Wage Change) for the Hampden, Massachusetts wage area (AC–039).
- 7. Wage Schedule (Wage Change) for the Middlesex, Massachusetts wage area (AC–138).
- 8. Wage Schedule (Wage Change) for the York, Maine wage area (AC–139).

Reviewing survey results and/or survey specifications for the following Appropriated Fund areas:

- 9. Survey Specifications for the Fresno, California wage area (AC–012).
- 10. Survey Specifications for the Louisville, Kentucky wage area (AC–059).
- 11. Any items needing further clarification from this agenda may be discussed during future scheduled meetings.

Closing Remarks by Chair.

December 13, 2022

Opening Remarks by Chair and DFO. Reviewing survey results and/or survey specifications for the following Nonappropriated Fund areas:

 Any items needing further clarification or action from the previous agenda.

2. Survey Specifications for the Richmond, Georgia wage area (AC–035).

3. Survey Specifications for the Houston, Georgia wage area (AC–036).

 Survey Specifications for the Pulaski, Arkansas wage area (AC–045).

- 5. Survey Specifications for the Montgomery, Alabama wage area (AC–048).
- 6. Survey Specifications for the Sedgwick, Kansas wage area (AC–078).
- 7. Survey Specifications for the Montgomery-Greene, Ohio wage area (AC–166).

Reviewing survey results and/or survey specifications for the following Appropriated Fund areas:

8. Wage Schedule (Full Scale) for the Bloomington-Bedford-Washington, Indiana wage area (AC–048).

- 9. Wage Schedule (Full Scale) for the Ft. Wayne-Marion, Indiana wage area (AC–049).
- 10. Wage Schedule (Full Scale) for the Indianapolis, Indiana wage area (AC–050).
- 11. Wage Schedule (Full Scale) for the Kansas City, Missouri wage area (AC–080).
- 12. Wage Schedule (Full Scale) for the St. Louis, Missouri wage area (AC–081).
- 13. Wage Schedule (Full Scale) for the Southern Missouri wage area (AC–082).
- 14. Wage Schedule (Full Scale) for the Omaha, Nebraska wage area (AC–084).

- 15. Wage Schedule (Full Scale) for the Dallas-Ft. Worth, Texas wage area (AC–131).
- 16. Wage Schedule (Wage Change) for the Cocoa Beach-Melbourne, Florida wage area (AC–028).
- 17. Wage Schedule (Wage Change) for the Davenport-Rock Island-Moline, Iowa wage area (AC–053).
- 18. Wage Schedule (Wage Change) for the Southwestern Michigan wage area (AC–073).
- 19. Wage Schedule (Wage Change) for the Philadelphia, Pennsylvania wage area (AC–115).
- 20. Wage Schedule (Wage Change) for the Eastern South Dakota wage area (AC-121).
- 21. Special Pay—Omaha, Nebraska Special Rates
- 22. Special Pay—Philadelphia, Pennsylvania Special Rates
- 23. Any items needing further clarification from this agenda may be discussed during future scheduled meetings.

Closing Remarks by Chair.

December 27, 2022

Opening Remarks by Chair and DFO. Reviewing survey results and/or survey specifications for the following Appropriated Fund areas:

- 1. Any items needing further clarification or action from the previous agenda.
- 2. Survey Specifications for the Northeastern Arizona wage area (AC–008).
- 3. Survey Specifications for the Tucson, Arizona wage area (AC–010).
- 4. Survey Specifications for the Northern New York wage area (AC–095).
- 5. Survey Specifications for the West Virginia wage area (AC–146).
- 6. Any items needing further clarification from this agenda may be discussed during future scheduled meetings.

Closing Remarks by Chair.

January 10, 2023

Opening Remarks by Chair and DFO. Reviewing survey results and/or survey specifications for the following Nonappropriated Fund areas:

- 1. Any items needing further clarification or action from the previous agenda.
- 2. Survey Specifications for the McLennan, Texas wage area (AC–022).
- 3. Survey Specifications for the Alleghany, Pennsylvania wage area (AC–066).
- 4. Survey Specifications for the Jefferson, New York area (AC-101).
- 5. Survey Specifications for the Orange, New York wage area (AC–103).

- 6. Survey Specifications for the Macomb, Michigan wage area (AC–162).
- 7. Survey Specifications for the Niagara, New York wage area (AC–166).

Reviewing survey results and/or survey specifications for the following Appropriated Fund areas:

- 8. Wage Schedule (Full Scale) for the New Orleans, Louisiana wage area (AC–061).
- 9. Wage Schedule (Full Scale) for the Richmond, Virginia area (AC–141).
- 10. Wage Schedule (Wage Change) for the Wilmington, Delaware wage area (AC–026).
- 11. Wage Schedule (Wage Change) for the Topeka, Kansas wage area (AC-056).
- 12. Wage Schedule (Wage Change) for the Wichita, Kansas wage area (AC–057).
- 13. Wage Schedule (Wage Change) for the Biloxi, Mississippi wage area (AC–076).
- 14. Wage Schedule (Wage Change) for the Roanoke, Virginia wage area (AC–142).
- 15. Survey Specifications for the Albuquerque, New Mexico wage area (AC–089).
- 16. Special Pay—Wilmington, Delaware Special Rates
- 17. Any items needing further clarification from this agenda may be discussed during future scheduled meetings.

Closing Remarks by Chair.

January 24, 2023

Opening Remarks by Chair and DFO. Reviewing survey results and/or survey specifications for the following Appropriated Fund areas:

- 1. Any items needing further clarification or action from the previous agenda.
- 2. Survey Specifications for the New Haven-Hartford, Connecticut wage area (AC-024).
- 3. Survey Specifications for the Cleveland, Ohio wage area (AC–105).
- 4. Survey Specifications for the Texarkana, Texas wage area (AC–136).
- 5. Any items needing further clarification from this agenda may be discussed during future scheduled meetings.

Closing Remarks by Chair.

February 7, 2023:

Opening Remarks by Chair and DFO. Reviewing survey results and/or survey specifications for the following Nonappropriated Fund areas:

- 1. Any items needing further clarification or action from the previous agenda.
- 2. Wage Schedule (Full Scale) for the Brevard, Florida wage area (AC–061).

- 3. Wage Schedule (Full Scale) for the Hillsborough, Florida wage area (AC–119).
- 4. Wage Schedule (Full Scale) for the Miami-Dade, Florida wage area (AC–158).
- 5. Wage Schedule (Full Scale) for the Duval, Florida wage area (AC–159).

6. Wage Schedule (Full Scale) for the Monroe, Florida wage area (AC–160).

- 7. Wage Schedule (Wage Change) for the Washoe-Churchill, Nevada wage area (AC–011).
- 8. Wage Schedule (Wage Change) for the Orange, Florida wage area (AC-062).
- 9. Wage Schedule (Wage Change) for the Bay, Florida wage area (AC-063).
- 10. Wage Schedule (Wage Change) for the Escambia, Florida wage area (AC– 064).
- 11. Wage Schedule (Wage Change) for the Okaloosa, Florida wage area (AC– 065)
- 12. Wage Schedule (Wage Change) for the Clark, Nevada wage area (AC–140).
- 13. Survey Specifications for the Orleans, Louisiana wage area (AC–006).
- 14. Survey Specifications for the Bell, Texas wage area (AC–028).
- 15. Survey Specifications for the Curry, New Mexico wage area (AC–030).
- 16. Survey Specifications for the Tom Green, Texas wage area (AC–032).
- 17. Survey Specifications for the Cobb, Georgia wage area (AC–034).
- 18. Survey Specifications for the Columbus, Georgia wage area (AC–067). Reviewing survey results and/or survey specifications for the following
- Appropriated Fund areas:
 1. Survey Specifications for the Atlanta, Georgia wage area (AC–037).
- 2. Survey Specifications for the Waco, Texas wage area (AC–137).
- 3. Any items needing further clarification from this agenda may be discussed during future scheduled meetings.

Closing Remarks by Chair.

Meeting Accessibility: Pursuant to 5
U.S.C. 552b(c)(4), the Department of
Defense has determined that the
meetings shall be closed to the public.
The Under Secretary of Defense for
Personnel and Readiness, in
consultation with the Department of
Defense Office of General Counsel, has
determined in writing that each of these
meetings is likely to disclose trade
secrets and commercial or financial
information obtained from a person and
privileged or confidential.

Written Statements: Pursuant to section 10(a)(3) of the Federal Advisory Committee Act and 41 CFR 102–3.140, interested persons may submit written statements to the DFO for the DoDWC at any time. Written statements should be submitted to the DFO at the email or

mailing address listed in the FOR FURTHER INFORMATION CONTACT section. If statements pertain to a specific topic being discussed at a planned meeting, then these statements must be submitted no later than five (5) business days prior to the meeting in question. Written statements received after this date may not be provided to or considered by the DoDWC until its next meeting. The DFO will review all timely submitted written statements and provide copies to all the committee members before the meeting that is the subject of this notice.

Dated: November 8, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–24722 Filed 11–10–22; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF EDUCATION

Accrediting Agencies Currently Undergoing Review for the Purposes of Recognition by the U.S. Secretary of Education

AGENCY: Accreditation Group, Office of Postsecondary Education, Accreditation Group, U.S. Department of Education.

ACTION: Call for written third-party comments.

SUMMARY: This notice provides information to members of the public on submitting written comments for accrediting agencies currently undergoing review for purposes of recognition by the U.S. Secretary of Education.

FOR FURTHER INFORMATION CONTACT:

Herman Bounds, Director, Accreditation Group, Office of Postsecondary Education, U.S. Department of Education, 400 Maryland Avenue SW, Room 2C158, Washington, DC 20202, telephone: (202) 453–7615, or email: herman.bounds@ed.gov.

SUPPLEMENTARY INFORMATION: This request for written third-party comments concerning the performance of accrediting agencies under review by the Secretary of Education is required by 496(n)(1)(A) of the Higher Education Act (HEA) of 1965, as amended, and pertains to the winter 2024 meeting of the National Advisory Committee on Institutional Quality and Integrity (NACIQI). The meeting date and location have not been determined but will be announced in a later Federal Register notice. In addition, a later Federal Register notice will describe how to register to provide oral comments at the meeting.

Agencies Under Review and Evaluation: The Department requests written comments from the public on the following accrediting agencies, which are currently undergoing review and evaluation by the Accreditation Group, and which will be reviewed at the winter 2024 NACIQI meeting.

The agencies are listed by the type of application each agency has submitted. Please note, each agency's current scope of recognition is indicated below. If any agency requests a change to its scope of recognition, identified are both the current scope of recognition and the requested scope of recognition.

Applications for Renewal of Recognition

1. The Kansas State Board of Nursing. Scope of Recognition: state agency for the approval of nurse education.

2. The Missouri State Board of Nursing. Scope of Recognition: state agency for the approval of nurse education.

3. The Oklahoma Department of Career and Technology Education. Scope of Recognition: the approval of public postsecondary vocational education offered at institutions in the State of Oklahoma that are not under the jurisdiction of the Oklahoma State Regents for Higher Education, including the approval of public postsecondary vocational education offered via distance education.

4. New York State Board of Regents (Public Postsecondary Vocational Ed). Scope of Recognition: state agency for the approval of public postsecondary vocational education in the field of practical nursing offered by a Board of Cooperative Educational Services, an Educational Opportunity Center, City School Districts, and County Boards of Supervisors to prepare persons for licensed practical nursing careers in the State of New York.

5. The Pennsylvania State Board for Career and Technical Education. Scope of Recognition: state agency for the approval of public postsecondary vocational education.

Compliance Reports

1. Accrediting Commission for Acupuncture and Herbal Medicine (ACAHM). Scope of recognition: the accreditation and pre-accreditation ("Candidacy") of professional nondegree and graduate degree programs, including professional doctoral programs, in the field of acupuncture and/or Oriental medicine, as well as freestanding institutions and colleges of acupuncture and/or Oriental medicine that offer such programs. Geographic Area of Accrediting Activities:

throughout the United States. Please note, this accrediting agency changed its name from "Accrediting Commission for Acupuncture and Oriental Medicine (ACAOM)" effective September 8, 2021.

The compliance report must address findings of noncompliance with 34 CFR 602, as referenced in the senior Department official's (SDO) decision letter dated October 27, 2021. The SDO also required that the Department staff 34 CFR 602.33 inquiry findings concerning the Seldin/Haring-Smith Foundation case study on Sex Trafficking and State Authorized Massage Schools, which involved an ACAHM accredited institution, be produced as part of the ACAHM compliance report. The SDO decision letter may be found under NACIQI meeting date July 27, 2021, available at: https://surveys.ope.ed.gov/erecognition/ #/public-documents

2. Council on Occupational Education. Scope of recognition: the accreditation and pre-accreditation ("Candidacy Status") of postsecondary occupational education institutions offering non-degree and applied associate degree programs in specific career and technical education fields, including institutions that offer programs via distance education. Geographic Area of Accrediting Activities: throughout the United States.

The compliance report must address findings of noncompliance with 34 CFR 602, as referenced in the SDO decision letter dated October 27, 2021. The SDO decision letter may be found under NACIQI meeting date July 27, 2021, available at: https://surveys.ope.ed.gov/erecognition/#/public-documents.

3. Transnational Association of Christian Colleges and Schools, Accreditation Commission. Scope of Recognition: the accreditation and preaccreditation ("Candidate" status) of Christian postsecondary institutions that offer certificates, diplomas, and associate, baccalaureate, and graduate degrees, including institutions that offer distance education. Geographic Area of Accrediting Activities: throughout the United States. The compliance report must address findings of noncompliance with 34 CFR 602, as referenced in the SDO decision letter dated October 27. 2021. The SDO decision letter may be found under NACIQI meeting date July 27, 2021, available at: https:// surveys.ope.ed.gov/erecognition/#/ public-documents.

Military Degree Granting Authority Substantive Change Approval in Accordance With Department of Defense DOD Instruction 5545.04

1. The National Defense University. Name Change of degree program from "Master of Science in Government Information Leadership" to "Master of Science in Strategic Information and Cyberspace Studies."

Expansion of Scope

1. National Nurse Practitioner
Residency and Fellowship Training
Consortium. Scope of Recognition: the
accreditation of nurse practitioner (NP)
postgraduate residency and fellowship
training programs. This recognition also
extends to the agency's Appeals Panel.
Requested Scope: the accreditation of
joint nurse practitioner/physician
assistant postgraduate residency and
fellowship training programs. This
recognition also extends to the agency's
Appeals Panel.

Submission of Written Comments Regarding a Specific Accrediting Agency Under Review

Written comments about the recognition of any of the accrediting agencies listed above must be received by December 12, 2022, in the ThirdPartyComments@ed.gov mailbox. Please include in the subject line "Written Comments: (agency name)." The electronic mail (email) must include the name(s), title, organization/ affiliation, mailing address, email address, and telephone number of the person(s) making the comment. Comments should be submitted as a PDF. Microsoft Word document or in a medium compatible with Microsoft Word that is attached to an email or provided in the body of an email message. Comments about an agency that has submitted a compliance report scheduled for review by the Department must relate to the criteria for recognition cited in the SDO's letter that requested the report, or in the Secretary's appeal decision, if any. Comments about an agency that has submitted a petition for initial recognition, renewal of recognition, or an expansion of scope must relate to the agency's compliance with the Criteria for the recognition of Accrediting Agencies or the Criteria for the recognition of state agencies, which are available at: https://www2.ed.gov/ admins/finaid/accred/index.html.

Only written materials submitted by the deadline to the email address listed in this notice, and in accordance with these instructions, become part of the official record concerning agencies scheduled for review and are considered by the Department and NACIQI in their deliberations.

Electronic Access to this Document: The official version of this document is the document published in the Federal **Register.** Free internet access to the official edition of the Federal Register and the Code of Federal Regulations is available via the Federal Digital System at: www.gpo.gov/fdsys. At this site, you can view this document, as well as all other documents of the Department published in the Federal Register, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site. You may also access documents of the Department published in the Federal Register by using the article search feature at: www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

(Authority: 20 U.S.C. 1011c; 20 U.S.C. 1099b)

Annmarie Weisman,

Deputy Assistant Secretary for Policy, Planning and Innovation, Office of Postsecondary Education.

[FR Doc. 2022-24637 Filed 11-10-22; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[Docket No. ED-2022-SCC-0111]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; IES Research Training Program Surveys

AGENCY: Institute of Education Sciences (IES), Department of Education (ED). **ACTION:** Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before December 14, 2022.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this information collection request (ICR) by selecting "Department of Education" under "Currently Under Review," then check the "Only Show ICR for Public Comment" checkbox. Reginfo.gov provides two links to view documents related to this information collection request. Information collection forms

and instructions may be found by clicking on the "View Information Collection (IC) List" link. Supporting statements and other supporting documentation may be found by clicking on the "View Supporting Statement and Other Documents" link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Meredith Larson, 202–245–7037.

SUPPLEMENTARY INFORMATION: The Department, 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 ICR that is described below. The Department is especially interested in public comments 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 record.

Title of Collection: IES Research Training Program Surveys.

OMB Control Number: 1850–0873. Type of Review: A revision of a currently approved collection.

Respondents/Affected Public: Individuals and Households.

Total Estimated Number of Annual Responses: 537.

Total Estimated Number of Annual Burden Hours: 180.

Abstract: The surveys are for participants in the fellowship research training programs and the nonfellowship research training programs funded by Institute of Education Sciences (IES). IES's fellowship programs include predoctoral training under the National Center for Education Research (NCER) and postdoctoral training under NCER and the National Center for Special Education Research (NCSER). These programs provide

universities support to provide training in education research and special education research to graduate students (predoctoral program) and postdoctoral fellows. IES also supports nonfellowship research training through its current programs, e.g., NCER's Methods Research Training program and NCER's Undergraduate Pathways program. IES would like to collect satisfaction information from the participants in these programs and other similar training programs funded through NCER or NCSER grant programs. The results of the surveys will be used both to improve the training programs as well as to provide information on the programs to the participants, policymakers, practitioners, and the general public. All information released to the public will be in aggregate so that no one program or training group can be distinguished.

Dated: November 8, 2022.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–24720 Filed 11–10–22; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: Bonneville Power Administration, Department of Energy. ACTION: Submission for Office of

ACTION: Submission for Office of Management and Budget (OMB) review; comment request.

SUMMARY: The Department of Energy (DOE) has submitted an information collection request to the OMB under the provisions of the Paperwork Reduction Act of 1995. The information collection requests a three-year approval of its collection, titled Contractor Safety, OMB Control Number 1910–NEW. The proposed collection, Contractor Safety, will be used to manage portions of the Safety program that are related to contractors. These collection instruments allow for compliance with Occupational Safety and Health Administration (OSHA) requirements.

DATES: Comments regarding this collection must be received on or before December 14, 2022. If you anticipate that you will be submitting comments but find it difficult to do so within the period allowed by this notice, please advise the OMB Desk Officer of your intention to make a submission as soon

as possible. The Desk Officer may be telephoned at 202–881–8585.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the information collection instrument and instructions should be directed to Attn: Stephanie Noell, Privacy Program, by email at *privacy@bpa.gov*, or by phone at (503) 230–3881.

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) OMB No.: 1910-NEW; (2) Information Collection Request Title: Contractor Safety; (3) Type of Request: New; (4) Purpose: This information collection will be used to manage BPA safety programs that relate to contractors: BPA F 5480.28e, Excavation/Trenching Permit, BPA F 6410.15e, Contractor's Report of Injury or Illness, BPA F 6410.18e, Contractor's Report of Incident/Near-Hit, BPA F 6410.42e, Contract Energized Electrical Work Permit; (5) Annual Estimated Number of Respondents: 190; (6) Annual Estimated Number of Total Responses: 190; (7) Annual Estimated Number of Burden Hours: 50; (8) Annual Estimated Reporting and Recordkeeping Cost Burden: \$0.

Statutory Authority: The Bonneville Project Act of 1937, 16 U.S.C 832a; and the following additional authorities: 42 U.S.C. 7101; 5 U.S.C. 301; 29 U.S.C. 657 and 29 CFR part 1926.

Signing Authority: This document of the Department of Energy was signed on November 4, 2022, by Candice D. Palen, Information Collection Clearance Manager, Bonneville Power Administration, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Signed in Washington, DC, on November 8, 2022.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2022-24667 Filed 11-10-22; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER23-375-000]

Colice Hall Solar, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Colice Hall Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 28, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at http://www.ferc.gov. To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the Federal **Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (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. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID-19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at FERCOnlineSupport@ferc.gov or call toll-free, (886) 208-3676 or TYY, (202) 502-8659.

Dated: November 7, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022-24696 Filed 11-10-22; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings in Existing Proceedings

Docket Numbers: RP23-77-001. Applicants: ANR Pipeline Company. Description: Tariff Amendment: Jackson Generation Amended NCNR Agmt No. 132120_2 to be effective 11/1/2022.

Filed Date: 11/4/22.

Accession Number: 20221104-5121. Comment Date: 5 p.m. ET 11/16/22.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

Filings Instituting Proceedings

Docket Numbers: RP23–170–000. Applicants: Wyoming Interstate Company, L.L.C.

Description: § 4(d) Rate Filing: Firm Daily Balancing Service Update to be effective 12/1/2022.

Filed Date: 11/4/22.

Accession Number: 20221104–5101. Comment Date: 5 p.m. ET 11/16/22. Docket Numbers: RP23–171–000. *Applicants:* Columbia Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Capacity Release Agreements—Vitol, Direct Energy and Constellation Energy to be effective 11/1/2022.

Filed Date: 11/4/22.

Accession Number: 20221104–5118. Comment Date: 5 p.m. ET 11/16/22. Docket Numbers: RP23–172–000. Applicants: Nautilus Pipeline

Company, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rates—Walter OG 630249 eff 11–7–22 to be effective 11/7/2022.

Filed Date: 11/7/22.

Accession Number: 20221107–5072. Comment Date: 5 p.m. ET 11/21/22.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (https://elibrary.ferc.gov/idmws/search/fercgensearch.asp) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: http://www.ferc.gov/docs-filing/efiling/filing-req.pdf. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 7, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–24697 Filed 11–10–22; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD22-12-000]

Joint FERC-DOE Supply Chain Risk Management, Technical Conference; Supplemental Notice of Technical Conference

Take notice that the Federal Energy Regulatory Commission (Commission) will convene a Joint Technical Conference with the U.S. Department of Energy in the above-referenced proceeding on December 7, 2022, from approximately 8:30 a.m. to 5:00 p.m. Eastern Time. The conference will be held in-person at the Commission's headquarters at 888 First Street NE, Washington, DC 20426 in the Commission Meeting Room.

The purpose of this conference is to discuss supply chain security challenges related to the Bulk-Power System, ongoing supply chain-related activities, and potential measures to secure the supply chain for the grid's hardware, software, computer, and networking equipment. FERC Commissioners and DOE's Office of Cybersecurity, Energy Security, and Emergency Response (CESER) Director will be in attendance, and panels will involve multiple DOE program offices, the North American Electric Reliability Corporation (NERC), trade associations, leading vendors and manufacturers, and

The conference will be open for the public to attend, and there is no fee for attendance. This notice provides additional information regarding each panel and seeks nominations for interested panelists. The Commission will issue a further supplemental notice with a full agenda and the list of panelists. Information on this technical conference will also be posted on the Calendar of Events on the Commission's website, www.ferc.gov, prior to the event.

The conference will also be transcribed. Transcripts will be available for a fee from Ace Reporting, (202) 347–3700.

Those who wish to nominate their names for consideration as a panel participant should submit their name, title, company (or organization they are representing), telephone, email, a one-paragraph biography, picture, and topic they wish to address to: 2022SupplyChainTechConference@ferc.gov by close of business on Friday, November 18, 2022.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to accessibility@ferc.gov, call toll-free (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 technical conference, please contact Simon Slobodnik at Simon.Slobodnik@ ferc.gov or (202) 502–6707. For information related to logistics, please contact Lodie White at Lodie.White@ ferc.gov or (202) 502–8453.

Dated: November 7, 2022. **Kimberly D. Bose,** *Secretary.*



Supply Chain Risk Management Technical Conference

Docket No. AD22-12-000

December 7, 2022, 8:30 a.m.-5:00 p.m.

8:30 a.m.—Opening Remarks and Introductions

9:00 a.m.—Panel I: Supply Chain Risks Facing the Bulk-Power System

The U.S. energy sector procures products and services from a globally distributed, highly complex, and increasingly interconnected set of supply chains. Information Technology (IT) and Operational Technology (OT) systems enable increased interconnectivity, process automation, and remote control. As a result, supply chain risks will continue to evolve and likely increase. This panel will discuss the state of supply chain risks from a national and geopolitical perspective. Specifically, the panel will explore current supply chain risks to the security of grid's hardware, software, computer, and networking equipment and how well-resourced campaigns perpetrated by nation states, such as the SolarWinds incident, affect supply chain risk for the electric sector. Panelists will discuss the origins of these risks, their pervasiveness, the possible impacts they could have on Bulk-Power System reliability, and approaches to mitigating them. The panelists will also discuss challenges associated with supply chain visibility and covert embedded spyware or other compromising software or hardware in suppliers' products, parts, or services.

This panel may include a discussion of the following topics and questions:

 Describe the types of challenges and risks associated with globally

- distributed, highly complex, and increasingly interconnected supply chains.
- 2. Describe the difficulties associated with supply chain visibility and how origins of products or components may be obscured.
- 3. How are foreign-supplied Bulk-Power System components being manipulated and is there a particular phase in the product lifecycle where the product is manipulated for nefarious intent?
- 4. How are these supply chain challenges and risks currently being managed?
- 5. How has the current geopolitical landscape impacted the energy sector's ability to manage supply chain challenges and risks?
- 6. How can Sector Risk Management Agencies and Regulators promote and/ or incentivize supply chain transparency at the earlier stages of product development and manufacturing?
- 7. Discuss the pathways (e.g., voluntary best practices and guidelines, mandatory standards) that together could address the current supply chain challenges and risks?
- 8. What actions can government take, both formal regulatory actions and coordination, to help identify and mitigate risks from the global supply chain for the energy sector?

 10:30 a.m.—Break

 10:45 a.m.—Panel II: Current Supply

10:45 a.m.—Panel II: Current Supply
Chain Risk Management (SCRM)
Reliability Standards, Implementation
Challenges, Gaps, and Opportunities
for Improvement

It has now been more than six years since the Commission directed the development of mandatory standards to address supply chain risks, and more than two years since the first set of those standards became effective. As discussed in Panel 1, supply chain risks have continued to grow in that time. In light of that evolving threat, panelists will discuss the existing SCRM Reliability Standards, including: (1) their effectiveness in securing the Bulk-Power System; (2) lessons learned from implementation of the current SCRM Reliability Standards; and (3) possible gaps in the currently effective SCRM Reliability Standards. This panel will also provide an opportunity to discuss any Reliability Standards in development, and how these new standards will help enhance security and help address some of the emerging supply chain threats.

This panel may include a discussion of the following topics and questions:

1. Are the currently effective SCRM Reliability Standards sufficient to

¹ See U.S. Dep't. of Energy, America's Strategy to Secure the Supply Chain for a Robust Clean Energy Transition: Response to Executive Order 14017, America's Supply Chains, 42, (Feb. 24, 2022), https://www.energy.gov/sites/default/files/2022-02/ America's%20Strategy%20to%20Secure%20the %20Supply%20Chain%20for%20a%20Robust%20 Clean%20Energy%20Transition%20FINAL.docx_ 0.pdf.

successfully ensure Bulk-Power System reliability and security in light of existing and emerging risks?

2. What requirements in the SCRM Reliability Standards present implementation challenges for registered entities and for vendors?

3. How are implementation challenges being addressed for utilities and for vendors?

4. Are there alternative methods for implementing the SCRM Reliability Standards that could eliminate challenges or enhance effectiveness moving forward?

5. Based on the current and evolving threat landscape, would the currently effective SCRM Reliability Standards benefit from additional mandatory security control requirements and how would these additional controls improve the security of the Bulk-Power System?

6. Are there currently effective SCRM criteria or standards that manufacturers must adhere to in foreign countries that may be prudent to adopt in the U.S.? 12:15 p.m.—Lunch

1:15 p.m.—Panel III: The U.S. Department of Energy's Energy Cyber

Sense Program

Through the Energy Cyber Sense Program, DOE will provide a comprehensive approach to securing the nation's critical energy infrastructure and supply chains from cyber threats with this voluntary program. The Energy Cyber Sense Program will build upon direction in Section 40122 of the Bipartisan Infrastructure Law, as well as multiple requests from industry, leveraging existing programs and technologies, while also initiating new efforts. Through Energy Cyber Sense, DOE aims to work with manufacturers and asset owners to discover, mitigate, and engineer out cyber vulnerabilities in digital components in the Energy Sector Industrial Base critical supply chains. This program will provide a better understanding of the impacts and dependencies of software and systems used in the energy sector; illuminate the digital provenance of subcomponents in energy systems, hardware, and software; apply best-in-class testing to discover and address common mode vulnerabilities; and provide education and awareness, across the sector and the broader supply chain community to optimize management of supply chain risks. This panel will discuss specific supply chain risks that Energy Cyber Sense will address as well as some of the programs and technologies DOE will bring to bear under the program to

address the risks. This panel may include a discussion of the following topics and questions:

1. How are emerging orders, standards, and process guidance, such as Executive Order 14017, Executive Order 14028, NIST Special Publication 800-161r1, ISA 62443, CIP-013-1, and others, changing how we assess our digital supply chain?

2. Given the dependence of OT on application-specific hardware, how could the inclusion and linkage of Hardware Bill of Materials (HBOMs) with Software Bill of Materials (SBOMs) increase our ability to accurately and effectively assess and mitigate supply chain risk? To what degree is this inclusion and linkage of HBOMs with SBOMs taking place today and what steps should be taken to fill any remaining gaps?

3. Given that much of the critical technology used in the energy sector is considered legacy technology, how can manufacturers, vendors, asset owners and operators, aided by the federal government, national laboratories, and other organizations, manage the supply chain risk from legacy technology? How can this risk management be coordinated with newer technologies that are more likely to receive SBOMs, HBOMs, and attestations?

4. Where does testing, for example Cyber Testing for Resilient Industrial Control Systems (CyTRICS) and thirdparty testing, fit in the universe of ʻrigorous and predictable mechanisms for ensuring that products function securely, and as intended?" 2

5. More than ever, developers are building applications on open-source software libraries. How can developers address the risks inherent with opensource software and how can asset owners work with vendors to validate that appropriate open-source risk management measures have been taken?

6. U.S. energy systems have significant dependencies on hardware components, including integrated circuits and semiconductors, most of which are manufactured outside of the US. What tools and technologies are needed to understand the provenance of hardware components used in U.S. energy systems and the risks from foreign manufacture? How will the newly passed CHIPS and Science Act change the risk landscape? What is needed in terms of regulation, standards, and other guidance to

strengthen the security of the hardware component supply chain from cyber and other risks?

2:45 p.m.—Break 3:00 p.m. Panel IV: Enhancing the Supply Chain Security Posture of the Bulk-Power System

This panel will discuss forwardlooking initiatives that can be used to improve the supply chain security posture of the Bulk-Power System. These initiatives could include vendor accreditation programs, product and service verification, improved internal supply chain security capability, third party services, and private and public

partnerships.

Vendor accreditation can be established in various ways. One of the more prominent ways is currently being explored by the North American Transmission Forum through its Supply Chain Security Assessment model and the associated questionnaire.³ The panel will also explore certain programs and practices used by utilities to verify the authenticity and effectiveness of products and services. Internal supply chain security capabilities include hiring people with the appropriate background and knowledge, while also developing relevant skills internally, through training on broad supply chain topics and applying them to the specific needs of the organization. Finally, this panel will address private and public partnerships on supply chain security and how they can facilitate timely access to information that will help better identify current and future supply chain threats to the Bulk-Power System and best practices to address those risks.

This panel may include a discussion of the following topics and questions:

1. What vendor accreditation programs currently exist or are in development? How can entities vet a vendor in the absence of a vendor accreditation program?

2. What are the challenges, benefits, and risks associated with utilizing thirdparty services for maintaining a supply chain risk management program?

3. What are the best practices and other guidance for security evaluation of vendors?

4. What programs and practices are currently in use to ensure product and service integrity?

5. What processes are used to test products prior to implementation?

6. What is the right balance between vendor and product security and cost? Is there a point of diminishing returns?

7. What are effective strategies for recruiting personnel with the

² See Exec. Order No. 14028, 86 FR 26,633, 26,646 (May 12, 2021) (The Executive Order declared that the security of software used by the Federal Government is "vital to the Federal Government's ability to perform its critical functions." The Executive Order further cited a "pressing need to implement more rigorous and predictable mechanisms for ensuring that products function securely, and as intended.")

³ https://www.natf.net/industry-initiatives/ supply-chain-industry-coordination.

appropriate background and SCRM skills to strengthen internal security practices? How do you provide the training necessary to further develop the skills specific to your unique organizational challenges?

8. What are the best ways to meaningfully assimilate SBOM information and what subsequent analyses can be done to strengthen internal security practices?

9. How can the industry keep informed of the latest supply chain compromises? How do entities currently respond to these compromises to keep their systems secure? Are there ways to improve these responses? What actions can government take, both formal regulatory actions and coordination, to help keep industry informed of supply

chain compromises and to facilitate

effective responses?

10. What key risk factors do entities need to consider prior to leveraging third party services and how should those risk factors be balanced with an entity's organizational policy? What SCRM controls do you have in place to ensure your systems and products have a reduced risk of compromise? Please discuss any challenges that you have experienced as well as successes.

11. How should government and industry prioritize and coordinate federal cross-agency and private sector collaboration and activities regarding SCRM?

4:45 p.m.—Closing Remarks 5:00 p.m.—Adjourn

[FR Doc. 2022–24710 Filed 11–10–22; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 298-000]

Southern California Edison Company; Notice of Authorization for Continued Project Operation

The license for the Kaweah Hydroelectric Project No. 298 was issued for a period ending December 31, 2021.

Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year-to-year an annual license to the then licensee(s) under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA, then, based on

section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license after the minor or minor part license expires, until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b), to continue project operations until the Commission issues someone else a license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 298 is issued to the Southern California Edison Company for a period effective January 1, 2022, through December 31, 2022, or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first. If issuance of a new license (or other disposition) does not take place on or before December 31, 2022, notice is hereby given that, pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the Commission, unless the Commission orders otherwise.

If the project is not subject to section 15 of the FPA, notice is hereby given that the Southern California Edison Company is authorized to continue operation of the Kaweah Hydroelectric Project under the terms and conditions of the prior license until the issuance of a new license for the project or other disposition under the FPA, whichever comes first.

Dated: November 7, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–24711 Filed 11–10–22; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC22–121–000; EC22–127–000.

Applicants: Desert Harvest II LLC, Desert Harvest, LLC, Milligan 1 Wind LLC, BigBeau Solar LLC, BigBeau Solar, LLC. Description: Response to October 27, 2022 Deficiency Letter of BigBeau Solar, LLC et al.

Filed Date: 11/3/22.

Accession Number: 20221103-5184. Comment Date: 5 p.m. ET 11/14/22.

Docket Numbers: EC23–23–000.
Applicants: ENBALA Power Networks

(USA), Inc.

Description: Application for Authorization Under Section 203 of the Federal Power Act of ENBALA Power Networks (USA) Inc.

Filed Date: 11/3/22.

Accession Number: 20221103-5186. Comment Date: 5 p.m. ET 11/25/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER23–376–000. Applicants: Oak Solar, LLC. Description: Baseline eTariff Filing: Co-Tenancy and Shared Facilities

Agreement to be effective 12/31/2022. Filed Date: 11/4/22.

Accession Number: 20221104–5133. Comment Date: 5 p.m. ET 11/25/22.

Docket Numbers: ER23–377–000. Applicants: PJM Interconnection,

L.L.C.

Description: § 205(d) Rate Filing: Original NSA, Service Agreement No. 6691; Queue No. AD2–115 to be effective 10/6/2022.

Filed Date: 11/7/22.

Accession Number: 20221107-5023. Comment Date: 5 p.m. ET 11/28/22.

Docket Numbers: ER23–378–000.
Applicants: PJM Interconnection,

Description: § 205(d) Rate Filing: ISA, Original SA No. 6667; Queue No. AE1–157 to be effective 10/7/2022.

Filed Date: 11/7/22.

Accession Number: 20221107-5043. Comment Date: 5 p.m. ET 11/28/22.

Docket Numbers: ER23–379–000.

Applicants: EWO Marketing, LLC.

Description: § 205(d) Rate Filing: SRPSA Capacity Rate Adjustment to be effective 1/1/2023.

Filed Date: 11/7/22.

Accession Number: 20221107–5057. Comment Date: 5 p.m. ET 11/28/22.

Docket Numbers: ER23–380–000.

Applicants: PacifiCorp.
Description: § 205(d) Rate Filing: Tri-

State—Heward Interconnection Agrmt to be effective 1/7/2023.

Filed Date: 11/7/22.

Accession Number: 20221107-5067. Comment Date: 5 p.m. ET 11/28/22.

Docket Numbers: ER23–381–000. Applicants: Midcontinent

Independent System Operator, Inc. Description: § 205(d) Rate Filing: 2022–11–07_SA 3393 Ameren IL- Sapphire Sky Wind 3rd Rev GIA (J826 J1022) to be effective 10/27/2022.

Filed Date: 11/7/22.

Accession Number: 20221107–5068. Comment Date: 5 p.m. ET 11/28/22.

Docket Numbers: ER23–382–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: Tariff Amendment: Notice of Cancellation of Rate Schedule FERC No. 252 to be effective 12/31/ 2022.

Filed Date: 11/7/22.

Accession Number: 20221107–5084. Comment Date: 5 p.m. ET 11/28/22.

Docket Numbers: ER23–383–000. Applicants: NorthWestern

Corporation.

Description: § 205(d) Rate Filing: RS 325 Revised and Amended LGIA to be effective 11/8/2022.

Filed Date: 11/7/22.

Accession Number: 20221107–5085. Comment Date: 5 p.m. ET 11/28/22.

Docket Numbers: ER23-384-000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: § 205(d) Rate Filing: Initial Filing of Rate Schedule FERC No. 350 to be effective 11/8/2022.

Filed Date: 11/7/22.

Accession Number: 20221107-5086. Comment Date: 5 p.m. ET 11/28/22.

Docket Numbers: ER23–385–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: § 205(d) Rate Filing: Amendment to Rate Schedule FERC No. 6 to be effective 1/3/2022.

Filed Date: 11/7/22.

Accession Number: 20221107-5087. Comment Date: 5 p.m. ET 11/28/22.

Docket Numbers: ER23–386–000. Applicants: PJM Interconnection,

L.L.C.

Description: § 205(d) Rate Filing: ISA, Original SA No. 6671; Queue No. AF1–038 to be effective 10/7/2022.

Filed Date: 11/7/22.

Accession Number: 20221107-5137. Comment Date: 5 p.m. ET 11/28/22.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES23–5–000. Applicants: New Hampshire Transmission, LLC.

Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of New Hampshire Transmission, LLC.

Filed Date: 11/3/22.

Accession Number: 20221103-5185. Comment Date: 5 p.m. ET 11/25/22.

The filings are accessible in the Commission's eLibrary system (https://elibrary.ferc.gov/idmws/search/

fercgensearch.asp) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: http://www.ferc.gov/docs-filing/efiling/filing-req.pdf. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 7, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–24698 Filed 11–10–22; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2022-0833; FRL-10361-01-ORD]

Availability of the IRIS Assessment Plan and Protocol for Assessing Cancer Risk From Inhalation Exposure to Cobalt and Cobalt Compounds

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a 30-day public comment period associated with release of the Integrated Risk Information System (IRIS) Assessment Plan and Systematic Review Protocol for Inhalation Exposure to Cobalt and Compounds (Cancer). This document communicates information on the scoping needs identified by EPA program and regional offices and the ĪRIS Program's initial problem formulation activities. Specifically, the assessment plan outlines the objectives for the IRIS assessment and the type of evidence considered most pertinent to address the scoping needs. The systematic review protocol describes the methodology of how the assessment will be conducted, including dose-response considerations. EPA is releasing this IRIS assessment plan and systematic review protocol for a 30-day public comment period in advance of a public science webinar planned for November 30, 2022. The Agency encourages the

public to comment on all aspects of the assessment plan and the systematic review protocol, including key science issues and identification of any new or missing studies.

DATES: The 30-day public comment period begins November 14, 2022 and ends December 14, 2022. Comments must be received on or before December 14, 2022.

ADDRESSES: The IRIS Assessment Plan and Systematic Review Protocol for Inhalation Exposure to Cobalt and Compounds (Cancer) will be available via the internet on the IRIS website at https://www.epa.gov/iris/iris-recent-additions and in the public docket at http://www.regulations.gov, Docket ID No. EPA-HQ-ORD-2022-0833.

FOR FURTHER INFORMATION CONTACT: For information on the public comment period, contact the ORD Docket at the EPA Headquarters Docket Center; telephone: 202–566–1752; facsimile: 202–566–9744; or email: Docket_ORD@epa.gov.

For technical information on the IRIS Assessment Plan and Systematic Review Protocol for Inhalation Exposure to Cobalt and Compounds (Cancer), contact Garland Waleko, CPHEA; email: Waleko.garland@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Information About IRIS Assessment Plans and Systematic Review Protocols

EPA's IRIS Program is a human health assessment program that evaluates quantitative and qualitative information on the health effects that may result from exposure to chemicals found in the environment. Through the IRIS Program, EPA provides high quality science-based human health assessments to support the Agency's regulatory activities and decisions to protect public health. As part of scoping and initial problem formulation activities prior to the development of an assessment, the IRIS Program carries out a broad, preliminary literature survey to assist in identifying health effects that have been studied in relation to the chemical or substance of interest, as well as science issues that may need to be considered when evaluating toxicity. This information, in conjunction with scoping needs identified by EPA program and regional offices, is used to inform the development of an IRIS assessment plan (IAP).

The IAP communicates the plan for developing each individual chemical assessment to the public and includes summary information on the IRIS Program's scoping and initial problem formulation activities, objectives and specific aims for the assessment, and a

PECO (Populations, Exposures, Comparators, and Outcomes) for the systematic review. The PECO provides the framework for developing detailed literature search strategies and inclusion/exclusion criteria, particularly with respect to evidence stream (e.g., human, animal, mechanistic), exposure measures, and outcome measures. EPA also presents a methods document, referred to as the systematic review protocol, for conducting a chemicalspecific systematic review of the available scientific literature. Systematic review protocols describe screening criteria to identify relevant literature, outline the approach for evaluating study quality, and describe the doseresponse methods.

II. Public Webinar Information

To allow for public input, EPA is convening a public webinar to discuss the IRIS Assessment Plan and Systematic Review Protocol for Inhalation Exposure to Cobalt and Compounds (Cancer) on November 30, 2022. Specific teleconference and webinar information regarding this public meeting will be provided through the IRIS website (https://www.epa.gov/ iris) and via EPA's IRIS listserv. To register for the IRIS listsery, visit the IRIS website (https://www.epa.gov/iris) or visit https://www.epa.gov/iris/forms/ staying-connected-integrated-riskinformation-system#connect.

III. How To Submit Technical Comments to the Docket at https:// www.regulations.gov

Submit your comments, identified by Docket ID No. EPA-HQ-ORD-2022-0833 for IRIS Assessment Plan and Systematic Review Protocol for Inhalation Exposure to Cobalt and Compounds (Cancer), by one of the following methods:

- www.regulations.gov: Follow the on-line instructions for submitting comments.
 - Email: Docket_ORD@epa.gov.
 - Fax: 202–566–9744.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center (ORD Docket), Mail Code: 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460. The phone number is 202– 566–1752.

Instructions: Direct your comments to Docket ID No. EPA-HQ-ORD-2022-0833. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked "late," and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to

make the comments available online at www.regulations.gov, including any personal information provided, unless a comment includes information claimed to be Confidential Business Information (CBI) or other information for which disclosure is restricted by statute. Do not submit information through www.regulations.gov or email that you consider to be CBI or otherwise protected. The www.regulations.gov website is an "anonymous access" system, which means 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 EPA without going through www.regulations.gov, vour 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, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at www.epa.gov/epahome/dockets.htm.

Docket: Documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other materials, such as copyrighted material, are publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the ORD Docket in the EPA Headquarters Docket Center.

Wayne Cascio,

Director, Center for Public Health & Environmental Assessment. [FR Doc. 2022–24684 Filed 11–10–22; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-10409-01-R3]

Delegation of Authority to the State of West Virginia To Implement and Enforce Additional or Revised National Emission Standards for Hazardous Air Pollutants Standards and New Source Performance Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of delegation of authority.

SUMMARY: On November 1, 2022, the Environmental Protection Agency (EPA) sent the State of West Virginia (West Virginia) a letter acknowledging that West Virginia's delegation of authority to implement and enforce the National Emissions Standards for Hazardous Air Pollutants (NESHAP) and New Source Performance Standards (NSPS) had been updated, as provided for under previously approved delegation mechanisms. To inform regulated facilities and the public, EPA is making available a copy of EPA's letter to West Virginia through this notice.

DATES: On November 1, 2022, EPA sent West Virginia a letter acknowledging that West Virginia's delegation of authority to implement and enforce Federal NESHAP and NSPS had been updated.

ADDRESSES: Copies of documents pertaining to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, Four Penn Center, 1600 JFK Boulevard, Philadelphia, Pennsylvania 19103. Copies of West Virginia's submittal are also available at the West Virginia Department of Environmental Protection, Division of Air Quality, 601 57th Street SE, Charleston, West Virginia 25304.

FOR FURTHER INFORMATION CONTACT:

Yongtian He, Permits Branch (3AD10), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, Four Penn Center, 1600 JFK Boulevard, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–2339. Mr. He can also be reached via electronic mail at *He.Yongtian@epa.gov.*

SUPPLEMENTARY INFORMATION: On July 1, 2022, West Virginia notified EPA that West Virginia had updated its incorporation by reference of Federal NESHAP and NSPS to include many such standards as found in Title 40 of the Code of Federal Regulations (CFR),

parts 60, 61, and 63 as of June 1, 2021. On November 1, 2022, EPA sent West Virginia a letter acknowledging that effective April 1, 2022, West Virginia has the authority to implement and enforce the NESHAP and NSPS as specified by West Virginia in its notices to EPA, as provided for under previously approved automatic delegation mechanisms (49 FR 48692, 67 FR 15486, EPA delegation letters dated March 19, 2001 and January 8, 2002). All notifications, applications, reports, and other correspondence required pursuant to the delegated NESHAP and NSPS must be submitted to both EPA Region III and to the West Virginia Department of Environmental Protection, unless the delegated standard specifically provides that such submittals may be sent to EPA or a delegated State. In such cases, the submittals should be sent only to the West Virginia Department of Environmental Protection. A copy of EPA's November 1, 2022 letter to West Virginia follows:

"Ms. Laura M. Crowder, Director, Division of Air Quality, West Virginia Department of Environmental Protection, 601 57th Street SE, Charleston, West Virginia 25304. Via email at laura.m.crowder@wv.gov Dear Ms. Crowder:

This letter acknowledges your letter dated July 1, 2022 in which the West Virginia Department of Environmental Protection (WVDEP) Division of Air Quality (DAQ) informed the United States Environmental Protection Agency (EPA) that West Virginia had updated its incorporation by reference of federal National Emissions Standards for Hazardous Air Pollutants (NESHAP) and New Source Performance Standards (NSPS) to include many such standards as found in 40 CFR parts 60, 61, and 63 as of June 1, 2021. WVDEP DAQ noted in the letter that it understood it was automatically delegated the authority to implement these standards. WVDEP DAQ stated its intent to enforce the standards in conformance with the terms of EPA's previous delegations of authority pursuant to the EPA final rules published at 49 FR 48692 and 67 FR 15486, and EPA delegation letters.

In two rulemakings, 49 FR 48692 (December 14, 1984) and 67 FR 15486 (April 2, 2002), EPA established the basis for delegation to West Virginia of specified federal standards at 40 CFR parts 60, 61, and 63. Subsequently, in a letter dated March 19, 2001 to WVDEP Director Michael Callaghan, EPA delegated to the State of West Virginia the authority to implement and enforce various federal NESHAP found in 40

CFR part 63. In another letter to Director Callaghan dated January 8, 2002, EPA delegated to the State of West Virginia the authority to implement and enforce various federal NESHAP found in 40 CFR part 61 and NSPS found in 40 CFR part 60. In those letters, EPA also established that future Part 60, Part 61, and Part 63 standards would be automatically delegated to West Virginia subject to the conditions set forth in those letters. Those rulemakings and letters continue to control the conditions of delegation of future standards and their terms should be consulted for the specific conditions that apply to each regulatory program. However, in general terms, for automatic delegation to take effect, the letters establish conditions that can be paraphrased as requiring: legal adoption of the standards; restrictions on the kinds of wording changes West Virginia may make to the federal standards when adopting them; and specific notification from West Virginia to EPA when a standard has been adopted.

WVDEP DAQ provided copies of the revised West Virginia Legislative Rules which specify the NESHAP and NSPS regulations West Virginia has adopted by reference. These revised Legislative Rules are entitled 45 CSR 34-"Emission Standards for Hazardous Air Pollutants," and 45 CSR 16—"Standards of Performance for New Stationary Sources." These revised Rules have an effective date of April 1, 2022. EPA has reviewed the Revised rules and determined that they meet the conditions for automatic delegation as established by EPA in its prior letters and rulemakings.

Accordingly, EPA acknowledges that West Virginia now has the authority, as provided for under the terms of EPA's previous delegation actions, to implement and enforce the NESHAP and NSPS standards which West Virginia adopted by reference in West Virginia's revised Legislative Rules 45 CSR 34 and 45 CSR 16, effective on April 1, 2022.

Please note that on December 19, 2008 in Sierra Club vs. EPA (551 F.3rd 1019, D.C. Circuit 2008), the United States Court of Appeals for the District of Columbia Circuit vacated certain provisions of the General Provisions of 40 CFR part 63 relating to exemptions for startup, shutdown, and malfunction (SSM). On October 16, 2009, the Court issued the mandate vacating these SSM exemption provisions, which are found at 40 CFR part 63, 63.6(f)(1), and (h)(1).

Accordingly, EPA no longer allows sources to use the SSM exemption as provided for in the vacated provisions at 40 CFR 63.6(f)(1), and (h)(1), even

though EPA has not yet formally removed the SSM exemption provisions from the General Provisions of 40 CFR part 63. Because West Virginia incorporated 40 CFR part 63 by reference, West Virginia should also no longer allow sources to use the former SSM exemption from the General Provisions of 40 CFR part 63 due to the Court's ruling in *Sierra Club* vs.*EPA* (551 F.3rd 1019, D.C. Circuit 2008). If you have any questions, please contact me or Ms. Arlin Galarza-Hernandez, Chief, Permits Branch, at 215–814–2041.

Cristina Fernández, Director, Air and Radiation Division

Enclosures

cc: Renu Chakrabarty (via email at renu.m.chakrabarty@wv.gov)
Mike Egnor (via email at michael.egnor@wv.gov)

This notice acknowledges the updates of West Virginia's delegation of authority to implement and enforce NESHAP and NSPS.

Cristina Fernández,

Director, Air and Radiation Division, Region III.

[FR Doc. 2022–24669 Filed 11–10–22; 8:45 am] BILLING CODE 6560–50–P

EXPORT IMPORT BANK

Privacy Act of 1974; Narrative Statement & System of Records Notice

AGENCY: Export Import Bank of the United States.

ACTION: Notice of new system of records.

SUMMARY: Pursuant to the Privacy Act of 1974, the Export Import Bank of the United States ("EXIM Bank") is proposing a new system of records notice ("SORN"). EXIM Bank is proposing a new system of records—EXIM Bank Watch List ("Watch List"). This new SORN will include the authorities for maintenance of the system, the purposes of the system, and the categories of entities and individuals covered by the system.

DATES: The modified system of records described herein will become applicable November 14, 2022.

ADDRESSES: You may submit written comments to EXIM Bank by any of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the website instructions for submitting comments.
- Email: reg.comments@exim.gov. Refer to SORN in the subject line.
- *Mail or Hand Delivery:* Office of Information and Privacy, Export Import

Bank of the United States, 811 Vermont Avenue NW, Washington, DC 20571.

Commenters are strongly encouraged to submit public comments electronically. EXIM Bank expects to have limited personnel available to process public comments that are submitted on paper through mail. Until further notice, any comments submitted on paper will be considered to the extent practicable.

All submissions must include the agency's name (Export Import Bank of the United States, or EXIM Bank) and reference this notice. Comments received will be posted without change to EXIM Bank's website, http:// www.exim.gov, including any personal information provided. Do not submit comments that include any personally identifiable information or confidential business information. Copies of comments may also be obtained by writing to Office of Information and Privacy, Export Import Bank of the United States, 811 Vermont Avenue NW, Washington, DC 20571.

FOR FURTHER INFORMATION CONTACT:

Marina Braginskaya, Senior Counsel for Litigation, Fraud & Compliance, Export Import Bank of the United States, 811 Vermont Avenue NW, Washington, DC 20571, 202-235-4687. For access to any of the EXIM Bank's systems of records, contact Dana Jackson Jr., Office of the General Counsel, 811 Vermont Avenue NW, Washington DC, 20571, or by calling 202-565-3168, or go to *Privacy* Act System of Records Notice (exim.gov).

SUPPLEMENTARY INFORMATION:

Narrative Statement

1. What is the purpose for establishing EXIM Watch List?

EXIM Watch List will provide a central repository of names of parties that have given rise to concerns by EXIM Bank personnel with a purpose:

- (1) to allow EXIM Bank to collect and maintain records of entities and individuals who participate in, or may be anticipated to participate in, EXIM Bank programs or activities who for one reason or another have given rise to reasonable concerns by EXIM Bank personnel;
- (2) to communicate, across EXIM Bank Divisions, any concerns EXIM Bank personnel might have about any entities/individuals; and
- (3) to address concerns by EXIM Bank and mitigate such concerns on a transaction-by-transaction basis.
- 2. What is the authority for maintaining EXIM Watch List?

Authority of the Export-Import Bank Act of 1945, as amended (12 U.S.C. 635

- et seq.), Executive Order 9397 as Amended by Executive Order 13478 signed by President George W. Bush on November 18, 2008, Relating to Federal Agency Use of Social Security Numbers.
- 3. What is the probable or potential effect of EXIM Watch List?

The probable or potential effect on the privacy of individuals is limited; access to records are restricted to individuals who have the appropriate clearance.

4. What steps will we take to minimize the risk of unauthorized access to EXIM Watch List?

EXIM Bank has established security and privacy protocols that meet the required security and privacy standards issued by the National Institute of Standards and Technology (NIST). Records are maintained in a secure, password protected electronic system that utilizes security hardware and software to include multiple firewalls, active intruder detection, and role-based access controls. EXIM Bank has adopted appropriate administrative, technical, and physical controls in accordance with EXIM Bank's security program to protect the confidentiality, integrity, and availability of the information, and to ensure that records are not disclosed to or accessed by unauthorized individuals.

5. Are the routine uses for EXIM Watch List compatible with the purpose for which they are collected?

The routine uses for this system of records are compatible with the purpose for which these records are collected. The proposed routine use is necessary and proper for the efficient and effective conduct of the Federal Government and to protect EXIM interests.

6. Are there any OMB Control Numbers, expiration dates, and titles of any information collection requests (e.g., forms, surveys, etc.) contained in EXIM Watch List and approved by OMB under the Paperwork Reduction Act? None.

EXIM Bank is establishing a new system of records, the Watch List. The Watch List is a due diligence and risk mitigation tool which acts as a central repository of names of parties that have given rise to concerns by EXIM Bank personnel. Parties are added to the Watch List when there is a reasonable basis to believe that the party had engaged in, or is associated with persons that have engaged in, either criminal conduct or conduct that could affect EXIM Bank adversely. The Watch List will be imbedded into the EXIM Online application system ("EOL") and/ or other application or screening systems. The Watch List is not an exclusion or debarment list.

SYSTEM NAME AND NUMBER:

EXIM Online (EOL)

SECURITY CLASSIFICATION:

Unclassified

SYSTEM LOCATION:

Export Import Bank of the United States, 811 Vermont Avenue NW, Washington, DC 20571. (Records may be kept at an additional location as backup for continuity of operations.)

SYSTEM MANAGER(S) AND ADDRESS:

Marina Braginskava, Senior Counsel for Litigation, Fraud & Compliance, EXIM Bank, 811 Vermont Avenue NW, Washington, DC 20571.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

EXIM Bank requests the information in this application under the following authorizations:

Authority of the Export-Import Bank Act of 1945, as amended (12 U.S.C. 635) et seq.), Executive Order 9397 as Amended by Executive Order 13478 signed by President George W. Bush on November 18, 2008, Relating to Federal Agency Use of Social Security Numbers.

PURPOSE(S) OF THE SYSTEM:

- (1) To allow EXIM Bank to collect and maintain records of entities and individuals who participate in, or may be anticipated to participate in, EXIM Bank programs or activities who for one reason or another have given rise to reasonable concerns by EXIM Bank personnel;
- (2) to communicate, across EXIM Bank Divisions, any concerns EXIM Bank personnel might have about any entities/individuals; and
- (3) to address concerns by EXIM Bank and mitigate such concerns on a transaction-by-transaction basis.

CATEGORIES OF INDIVIDUALS COVERED BY THE

Covered entities and individuals are: suspicious EXIM Bank applicants,

- or their owners, officers, directors or representatives.
- suspicious EXIM Bank participants, or their owners, officers, directors or representatives.
- those who raise reasonable suspicion that the party had engaged in, or is associated with persons that have engaged in, either criminal conduct or conduct that could affect EXIM Bank or the U.S. Government adversely.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual records in the Watch List include full name, company name, address.

RECORD SOURCE CATEGORIES:

The primary source of information is from referrals by EXIM Bank personnel and EXIM Bank's Office of Inspector General.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information about covered individuals may be disclosed without consent as permitted by the Privacy Act of 1974, 5 U.S.C. 552a(b), and:

- 1. General Routine Uses G1 through G14 apply to this system of records (see Prefatory Statement of General Routine Uses).
- 2. A record from this system may be disclosed to appropriate third-parties contracted by the Agency to facilitate mediation or other dispute resolution procedures or programs.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained manually in electronic form.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by any one or more of the following: individual name or business entity name.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are maintained and destroyed in accordance with the National Archives and Record Administration's ("NARA") Basic Laws and Authorities (44 U.S.C. 3301, et seq.) or an EXIM Bank records disposition schedule approved by NARA.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

EXIM Bank has established security and privacy protocols that meet the required security and privacy standards issued by the National Institute of Standards and Technology (NIST). Records are maintained in a secure, password protected electronic system that utilizes security hardware and software to include multiple firewalls, active intruder detection, and role-based access controls. EXIM Bank has adopted appropriate administrative, technical, and physical controls in accordance with EXIM Bank's security program to protect the confidentiality, integrity, and availability of the information, and to ensure that records are not disclosed to or accessed by unauthorized individuals.

Electronic records are stored on computer networks, which may include cloud-based systems, and protected by controlled access with Personal Identity Verification (PIV) cards, assigning user accounts to individuals needing access to the records and by passwords set by authorized users that must be changed periodically.

Information will be stored in electronic format within EOL, EOL has configurable, layered data sharing and permissions features to ensure users have proper access. Access to EOL is restricted to EXIM Bank personnel who need it for their job. Authorized users are limited to the Office of the General Counsel staff and they have access to the data and functions required to perform their job functions. Based on user role assignment, it is determined whether a specific user is provided "view-only" or "read-write" access to the data. These privileges are managed via EOL's System Administration, user, and security functions.

RECORD ACCESS PROCEDURES:

Requests to access records under the Privacy Act must be submitted in writing and must be signed by the requestor. Requests should be addressed to the Freedom of Information and Privacy Office, Export Import Bank of the United States, 811 Vermont Ave. NW, Washington, DC 20571. The request must comply with the requirements of 12 CFR 404.14.

CONTESTING RECORD PROCEDURES:

Individuals seeking to contest and/or amend records under the Privacy Act must submit a request in writing. The request must be signed by the requestor and should be addressed to the Freedom of Information and Privacy Office, Export Import Bank of the United States, 811 Vermont Ave. NW, Washington, DC 20571. The request must comply with the requirements of 12 CFR 404.14.

NOTIFICATION PROCEDURES:

Individuals seeking to be notified if this system contains a record pertaining to himself or herself must submit a request in writing. The request must be signed by the requestor and should be addressed to the Freedom of Information and Privacy Office, Export Import Bank of the United States, 811 Vermont Ave. NW, Washington, DC 20571. The request must comply with the requirements of 12 CFR 404.14.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Joyce B. Stone,

 $Assistant\ Corporate\ Secretary.$ [FR Doc. 2022–24726 Filed 11–10–22; 8:45 am]

BILLING CODE 6690-01-P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Revision of Information Collection; FDIC National Survey of Unbanked and Underbanked Households; Comment Request (3064– 0215)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to take this opportunity to comment on the survey collection instrument for its eighth biennial survey of households, which has been renamed the FDIC National Survey of Unbanked and Underbanked Households (Household Survey). This survey was previously named the Survey of Household Use of Banking and Financial Services and is assigned OMB Control No. 3064-0215. The 2023 Household Survey is scheduled to be conducted in partnership with the U.S. Census Bureau as a supplement to its June 2023 Current Population Survey (CPS). The survey collects information on U.S. households' use of bank accounts, prepaid cards, nonbank online payment services and other nonbank financial transaction services, and bank and nonbank credit. The results of these biennial surveys will be published by the FDIC, and help inform policymakers, bankers, and researchers about bank account ownership and household use of the banking system and nonbank financial products and services to meet their financial needs.

DATES: Comments must be submitted on or before January 13, 2023.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- Agency Website: https:// www.fdic.gov/resources/regulations/ federal-register-publications/.
- 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), Regulatory 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 NW building (located on F Street NW) on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to "Household Survey." 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, Regulatory Counsel, 202–898–3767, mcabeza@fdic.gov, MB– 3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: The FDIC is requesting OMB approval for the following collection of information:

Title: FDIC National Survey of Unbanked and Underbanked Households.

OMB Number: 3064–0215. Frequency of Response: Once. Affected Public: Individuals residing in U.S. Households.

Estimated Number of Respondents: 40.000.

Average Time per Response: 9 minutes (0.15 hours) per respondent. Estimated Total Annual Burden: 6.000 hours.

General Description of Collection: The FDIC is committed to expanding Americans' access to safe, secure, and affordable banking services, which is integral to the FDIC's mission of maintaining the stability of and public confidence in the U.S. financial system. The FDIC National Survey of Unbanked and Underbanked Households (Household Survey) is one contribution to this end. The Household Survey is also a key component of the FDIC's compliance with a Congressional mandate contained in section 7 of the Federal Deposit Insurance Reform Conforming Amendments Act of 2005 (Reform Act) (Pub. L. 109-173), which calls for the FDIC to conduct ongoing surveys "on efforts by insured depository institutions to bring those individuals and families who have rarely, if ever, held a checking account, a savings account or other type of transaction or check cashing account at an insured depository institution (hereafter in this section referred to as the 'unbanked') into the conventional finance system." Section 7 further instructs the FDIC to consider several factors in its conduct of the surveys, including: (1) "what cultural, language and identification issues as well as transaction costs appear to most prevent 'unbanked' individuals from establishing conventional accounts;" and (2) "what is a fair estimate of the size and worth of the "unbanked" market in the United States."

The Household Survey collects information on bank account ownership which provides a factual basis for measuring the number and percentage of households that are unbanked. The Household Survey is the only population-representative survey conducted at the national level that provides state-level estimates of the size and characteristics of unbanked households for all 50 states and the District of Columbia. The Household Survey also collects information from unbanked households about the reasons that they do not have a bank account and their interest in having a bank account. Increasingly, financial products and services are provided by nonbanks, many through the use of a mobile phone app. Households are selecting different combinations of bank and nonbank financial products and services to meet their core financial needs. Consequently, the Household Survey collects information on whether and how households use a wide range of bank and nonbank financial products and services.

To obtain this information, the FDIC partners with the U.S. Census Bureau, which administers the Household Survey supplement (FDIC Supplement) to households that participate in the Current Population Survey (CPS). The supplement has been administered every other year since January 2009. The previous survey questionnaires and survey results can be accessed through the following link: http://fdic.gov/analysis/household-survey.

Consistent with the statutory mandate to conduct the surveys on an ongoing basis, the FDIC already has in place arrangements for conducting the eighth Household Survey as a supplement to the June 2023 CPS. Prior to finalizing the 2023 survey questionnaire, the FDIC seeks to solicit public comment on whether changes to the existing instrument are desirable and, if so, to what extent. It should be noted that, as a supplement of the CPS survey, the Household Survey needs to adhere to specific parameters that include limits in the length and sensitivity of the questions that can be asked of CPS respondents. Interested members of the public may obtain a copy of the proposed survey questionnaire on the following web page: https:// www.fdic.gov/resources/regulations/ federal-register-publications/2023/2023household-survey-questionnaire.pdf.

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 collections, 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 November 7, 2022.

James P. Sheesley,

Assistant Executive Secretary.
[FR Doc. 2022–24642 Filed 11–10–22; 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 (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 applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at https://www.federalreserve.gov/foia/ request.htm. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than November 29, 2022.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. Elizabeth J.C. Brennan, West Des Moines, Iowa; to become the largest individual shareholder and join the Brennan Family control group, a group acting in concert, by acquiring voting shares of Morning Sun Bank Corp., and thereby indirectly acquiring voting shares of Bank, both of Wapello, Iowa.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board. [FR Doc. 2022–24620 Filed 11–10–22; 8:45 am] BILLING CODE P

FEDERAL TRADE COMMISSION

[File No. 202 3151]

Chegg, Inc.; Analysis of Proposed Consent Order To Aid Public Comment

AGENCY: Federal Trade Commission. **ACTION:** Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis of Proposed Consent Order to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before December 14, 2022.

ADDRESSES: Interested parties may file comments online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION section** below. Please write "Chegg, Inc.; File No. 202 3151" on your comment and file your comment online at https:// www.regulations.gov by following the instructions on the web-based form. If you prefer to file your comment on paper, please mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex D), Washington, DC

FOR FURTHER INFORMATION CONTACT:

Brian Shull (202–326–3734) or Genevieve Bonan (202–326–3139), Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule § 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final

approval, by the Commission, has been placed on the public record for a period of 30 days. The following Analysis to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained at https://www.ftc.gov/news-events/commission-actions.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before December 14, 2022 Write "Chegg, Inc.; File No. 202 3151" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the https://www.regulations.gov website.

Because of heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the https://www.regulations.gov website.

If you prefer to file your comment on paper, write "Chegg, Inc.; File No. 202 3151" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580

Because your comment will be placed on the publicly accessible website at https://www.regulations.gov, you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule § 4.10(a)(2), 16 CFR 4.10(a)(2)—including competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule § 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule § 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the https://www.regulations.gov website—as legally required by FTC Rule § 4.9(b) we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule § 4.9(c), and the General Counsel grants that request.

Visit the FTC website at http:// www.ftc.gov to read this document and the news release describing the proposed settlement. The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments it receives on or before December 14, 2022. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see https://www.ftc.gov/siteinformation/privacy-policy.

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an agreement containing a consent order from Chegg, Inc. ("Respondent"). The proposed consent order ("Proposed Order") has been placed on the public record for 30 days for receipt of public comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the agreement, along with the comments received, and will decide whether it should make final the Proposed Order or withdraw from the agreement and take appropriate action.

Respondent is a Delaware corporation with its principal place of business in California. Respondent offers an online platform through which consumers utilize Respondent's subscription-based study aids, which have included tutoring, writing assistance, mathproblem solvers, and answers to

common textbook questions. Respondent also has helped consumers search for potential scholarship opportunities. While using its services, Respondent's tens of millions of users have provided the company with their email addresses, first and last names, and passwords. Users of the scholarship search service have also provided Respondent with their religious denominations, heritages, dates of birth, parents' income ranges, sexual orientations, and disabilities. In addition, Respondent collects Social Security numbers, financial account information, and other personal information from its employees.

Despite representing to consumers that it would keep their sensitive information safe, Respondent failed to utilize reasonable information security measures to do so. As a result of Respondent's inadequate information security practices, hackers infiltrated Respondent's networks and accessed consumers' personal information on multiple occasions over the course of several years.

The Commission's proposed twocount complaint alleges Respondent violated Section 5(a) of the FTC Act by (1) failing to employ reasonable information security practices to protect consumers' personal information, and (2) misrepresenting to consumers that it took reasonable steps to protect their personal information. With respect to the first count, the proposed complaint

- alleges Respondent: failed to implement reasonable access controls to safeguard users personal information by failing to (1) require employees and third-party contractors to use distinct access keys to databases containing users' personal information, instead allowing them to use a single access key with full administrative privileges, (2) restrict access to systems based on employees' or contractors' job functions, (3) require multi-factor authentication for employee and contractor account access to users' personal information, and (4) rotate access keys to databases containing users' personal information;
- stored users' and employees' personal information on its network and databases in plain text, rather than encrypting the information;
- used outdated and unsecure cryptographic hash functions to protect users' passwords;
- failed to develop, implement, or maintain adequate written organizational information security standards, policies, procedures, or practices;
- failed to provide adequate guidance or training for employees or contractors

regarding information security and safeguarding consumers' personal information;

- failed to have a policy, process, or procedure for inventorying and deleting users' and employees' personal information stored on Respondent's network after that information was no longer needed; and
- failed to adequately monitor its networks and systems for unauthorized attempts to transfer or exfiltrate users and employees' personal information outside of Respondent's network boundaries.

The proposed complaint alleges Respondent could have addressed each of these failures by implementing readily available and relatively low-cost security measures. It also alleges Respondent's failures caused, or are likely to cause, substantial injury to consumers that is not outweighed by countervailing benefits to consumers or competition and is not reasonably avoidable by consumers themselves. Such practices constitute unfair acts or practices under Section 5 of the FTC Act.

With respect to the second count, the proposed complaint alleges that, at various times, Respondent claimed it used reasonable measures to protect personal information of consumers. The proposed complaint alleges in reality, and as noted above, Respondent failed to implement reasonable measures to protect consumers' personal information. Such representations were, therefore, deceptive under Section 5 of the FTC Act.

Summary of Proposed Order With Respondent

The Proposed Order contains injunctive relief designed to prevent Respondent from engaging in the same or similar acts or practices in the future. Part I prohibits Respondent from misrepresenting the extent to which it (1) collects, maintains, uses, discloses, deletes, or permits or denies access to consumers' personal information, and (2) protects the privacy, security, availability, confidentiality, or integrity of consumers' personal information. Part II requires that Respondent (1) document and adhere to a retention schedule for the personal information it collects from consumers, including the purposes for which it collects such information and the timeframe for its deletion, and (2) provide an opportunity for consumers to request access to, and/ or deletion of, their personal information.

Part III requires that Respondent provide multi-factor authentication methods as an option for users of its

services. Part IV requires that Respondent provide notice to any consumer whose Social Security number, financial information, date of birth, user account credentials, or medical information was exposed in a breach identified in the proposed complaint, provided the consumer has not previously received such notice.

Part V requires Respondent to establish and implement, and thereafter maintain, a comprehensive information security program that protects the security, availability, confidentiality, and integrity of consumers' personal information. Part VI requires Respondent to obtain initial and biennial information security assessments by an independent, thirdparty professional for 20 years. Part VII requires Respondent to disclose all material facts to the assessor required by Part VI and prohibits Respondent from misrepresenting any fact material to the assessments required by Part V.

Part VIII requires Respondent to submit an annual certification from a senior corporate manager (or senior officer responsible for its information security program) that the company has implemented the requirements of the Order and is not aware of any material noncompliance that has not been corrected or disclosed to the Commission. Part IX requires Respondent to notify the Commission any time it notifies a federal, state, or local government that consumer personal information was, or is reasonably believed to have been, accessed, acquired, or publicly exposed without authorization.

Parts X-XIII are reporting and compliance provisions, which include recordkeeping requirements and provisions requiring Respondent to provide information or documents necessary for the Commission to monitor compliance. Part XIV states the Proposed Order will remain in effect for 20 years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the Proposed Order, and it is not intended to constitute an official interpretation of the complaint or Proposed Order, or to modify the Proposed Order's terms in any way.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2022-24690 Filed 11-10-22: 8:45 am] BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1792-NC]

Medicare and Medicaid Programs; Announcement of Application From a Hospital Requesting Waiver for Organ Procurement Service Area

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS. **ACTION:** Notice with request for comment.

SUMMARY: This notice acknowledges the receipt of an application from a hospital that has requested a waiver of statutory requirements that would otherwise require the hospital to enter into an agreement with its designated organ procurement organization (OPO). This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant the requested waiver. **DATES:** Comment date: To be assured consideration, comments must be received at one of the addresses provided below, by January 13, 2023. ADDRESSES: In commenting, refer to file code CMS-1792-NC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

- 1. *Electronically*. You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the "Submit a comment" instructions.
- 2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1792-NC, P.O. Box 8010, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1792-NC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: Caitlin Bailey, (410) 786–9768.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of

the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: http:// www.regulations.gov. Follow the search instructions on that website to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

Organ Procurement Organizations (OPOs) are not-for-profit organizations that are responsible for the procurement, preservation, and transport of organs to transplant centers throughout the country. Qualified OPOs are designated by the Centers for Medicare & Medicaid Services (CMS) to recover or procure organs in CMSdefined exclusive geographic service areas, pursuant to section 371(b)(1) of the Public Health Service Act (42 U.S.C. 273(b)(1)) and our regulations at 42 CFR 486.306. Once an OPO has been designated for an area, hospitals in that area that participate in Medicare and Medicaid are required to work with that OPO in providing organs for transplant, pursuant to section 1138(a)(1)(C) of the Social Security Act (the Act) and our regulations at 42 CFR 482.45.

Section 1138(a)(1)(A)(iii) of the Act provides that a hospital must notify the designated OPO (for the service area in which it is located) of potential organ donors. Under section 1138(a)(1)(C) of the Act, every hospital must have an agreement only with its designated OPO to identify potential donors.

However, section 1138(a)(2)(A) of the Act provides that a hospital may obtain a waiver of the above requirements from the Secretary of the Department of Health and Human Services (the Secretary) under certain specified conditions. A waiver allows the hospital to have an agreement with an OPO other than the one designated by CMS, if the hospital meets certain conditions specified in section 1138(a)(2)(A) of the Act. In addition, the Secretary may review additional criteria described in section 1138(a)(2)(B) of the Act to

evaluate the hospital's request for a waiver.

Section 1138(a)(2)(A) of the Act states that in granting a waiver, the Secretary must determine that the waiver—(1) is expected to increase organ donations; and (2) will ensure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver. In making a waiver determination, section 1138(a)(2)(B) of the Act provides that the Secretary may consider, among other factors: (1) cost-effectiveness; (2) improvements in quality; (3) whether there has been any change in a hospital's designated OPO due to the changes made in definitions for metropolitan statistical areas; and (4) the length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO. Under section 1138(a)(2)(D) of the Act, the Secretary is required to publish a notice of any waiver application received from a hospital within 30 days of receiving the application, and to offer interested parties an opportunity to submit comments during the 60-day comment period beginning on the publication date in the **Federal Register**.

The criteria that the Secretary uses to evaluate the waiver in these cases are the same as those described above under section 1138(a)(2)(A) and (B) of the Act and have been incorporated into the regulations at § 486.308(e) and (f).

II. Waiver Request Procedures

In October 1995, we issued a Program Memorandum (Transmittal No. A–95–11) detailing the waiver process and discussing the information hospitals must provide in requesting a waiver. We indicated that upon receipt of a waiver request, we would publish a **Federal Register** notice to solicit public comments, as required by section 1138(a)(2)(D) of the Act.

According to these requirements, we will review the comments received. During the review process, we may consult on an as-needed basis with the Health Resources and Services Administration's Division of Transplantation, the United Network for Organ Sharing, and our regional offices. If necessary, we may request additional clarifying information from the applying hospital or others. We will then make a final determination on the waiver request and notify the hospital and the designated and requested OPOs.

III. Hospital Waiver Request

As permitted by § 486.308(e), the following hospital has requested a waiver to enter into an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located:

Mooresville Hospital Management Associates, LLC d/b/a Lake Norman Regional Medical Center, Mooresville, North Carolina, is requesting a waiver to work with: LifeShare Carolinas, 5000 D Airport Center Parkway, Charlotte, North Carolina 28208.

The Hospital's Designated OPO is: HonorBridge, 1430 WestBrook Plaza Drive, Winston-Salem, North Carolina 27103.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

V. Response to Comments

We will consider all comments we receive by the date specified in the **DATES** section of this preamble.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the Federal Register.

Dated: November 8, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–24716 Filed 11–10–22; 8:45 am] BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1791-NC]

Medicare and Medicaid Programs; Announcement of Application From a Hospital Requesting Waiver for Organ Procurement Service Area

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS. **ACTION:** Notice with request for comment.

SUMMARY: This notice acknowledges the receipt of an application from a hospital that has requested a waiver of statutory requirements to enter into an agreement with an organ procurement organization (OPO) other than its designated organ procurement organization. This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant the requested waiver.

DATES: Comment date: To be assured consideration, comments must be received at one of the addresses provided below, by January 13, 2023. **ADDRESSES:** In commenting, refer to file code CMS-1791-NC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

- 1. *Electronically*. You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the "Submit a comment" instructions.
- 2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1791-NC, P.O. Box 8010, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1791-NC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore MD 21244-1850.

For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: Caitlin Bailey, (410) 786–9768.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: http:// www.regulations.gov. Follow the search instructions on that website to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage

individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

Organ Procurement Organizations (OPOs) are not-for-profit organizations that are responsible for the procurement, preservation, and transport of organs to transplant centers throughout the country. Qualified OPOs are designated by the Centers for Medicare & Medicaid Services (CMS) to recover or procure organs in CMSdefined exclusive geographic service areas, pursuant to section 371(b)(1) of the Public Health Service Act (42 U.S.C. 273(b)(1)) and our regulations at 42 CFR 486.306. Once an OPO has been designated for an area, hospitals in that area that participate in Medicare and Medicaid are required to work with that OPO in providing organs for transplant, pursuant to section 1138(a)(1)(C) of the Social Security Act (the Act) and our regulations at 42 CFR 482.45.

Section 1138(a)(1)(A)(iii) of the Act provides that a hospital must notify the designated OPO (for the service area in which it is located) of potential organ donors. Under section 1138(a)(1)(C) of the Act, every hospital must have an agreement only with its designated OPO to identify potential donors.

However, section 1138(a)(2)(A) of the Act provides that a hospital may obtain a waiver of the above requirements from the Secretary of the Department of Health and Human Services (the Secretary) under certain specified conditions. A waiver allows the hospital to have an agreement with an OPO other than the one designated by CMS, if the hospital meets certain conditions specified in section 1138(a)(2)(A) of the Act. In addition, the Secretary may review additional criteria described in section 1138(a)(2)(B) of the Act to evaluate the hospital's request for a waiver.

Section 1138(a)(2)(A) of the Act states that in granting a waiver, the Secretary must determine that the waiver—(1) is expected to increase organ donations; and (2) will ensure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver. In making a waiver determination, section 1138(a)(2)(B) of the Act provides that the Secretary may consider, among other factors: (1) cost-effectiveness; (2) improvements in quality; (3) whether

there has been any change in a hospital's designated OPO due to the changes made in definitions for metropolitan statistical areas; and (4) the length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO. Under section 1138(a)(2)(D) of the Act, the Secretary is required to publish a notice of any waiver application received from a hospital within 30 days of receiving the application, and to offer interested parties an opportunity to submit comments during the 60-day comment period beginning on the publication date in the Federal Register.

The criteria that the Secretary uses to evaluate the waiver in these cases are the same as those described above under section 1138(a)(2)(A) and (B) of the Act and have been incorporated into the regulations at § 486.308(e) and (f).

II. Waiver Request Procedures

In October 1995, we issued a Program Memorandum (Transmittal No. A–95–11) detailing the waiver process and discussing the information hospitals must provide in requesting a waiver. We indicated that upon receipt of a waiver request, we would publish a **Federal Register** notice to solicit public comments, as required by section 1138(a)(2)(D) of the Act.

According to these requirements, we will review the comments received. During the review process, we may consult on an as-needed basis with the Health Resources and Services Administration's Division of Transplantation, the United Network for Organ Sharing, and our regional offices. If necessary, we may request additional clarifying information from the applying hospital or others. We will then make a

final determination on the waiver request and notify the hospital and the designated and requested OPOs.

III. Hospital Waiver Request

As permitted by § 486.308(e), the following hospital has requested a waiver to enter into an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located:

North Carolina Baptist Hospital, Winston-Salem, North Carolina, is requesting a waiver to work with: LifeShare Carolinas, 5000 D Airport Center Parkway, Charlotte, North Carolina 28208.

The Hospital's Designated OPO is: HonorBridge, 1430 WestBrook Plaza Drive, Winston-Salem, North Carolina 27103.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

V. Response to Comments

We will consider all comments we receive by the date specified in the **DATES** section of this preamble.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for

purposes of publication in the **Federal Register**.

Dated: November 8, 2022.

Lynette Wilson,

 $Federal\ Register\ Liaison,\ Centers\ for\ Medicare$ & Medicaid\ Services.

[FR Doc. 2022–24715 Filed 11–10–22; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9138-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July Through September 2022

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other Federal Register notices that were published from April through June 2022, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone number
I CMS Manual Instructions II Regulation Documents Published in the Federal Register III CMS Rulings IV Medicare National Coverage Determinations V FDA-Approved Category B IDEs VI Collections of Information VII Medicare-Approved Carotid Stent Facilities VIII American College of Cardiology-National Cardiovascular Data Registry Sites IX Medicare's Active Coverage-Related Guidance Documents X One-time Notices Regarding National Coverage Provisions XI National Oncologic Positron Emission Tomography Registry Sites XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Ismael Torres Terri Plumb Tiffany Lafferty Wanda Belle, MPA John Manlove William Parham Sarah Fulton, MHS JoAnna Baldwin, MS JoAnna Baldwin, MS David Dolan, MBA David Dolan, MBA Sarah Fulton, MHS	(410) 786–1864 (410) 786–4481 (410) 786–7548 (410) 786–7491 (410) 786–6877 (410) 786–2749 (410) 786–2749 (410) 786–2749 (410) 786–7205 (410) 786–3365 (410) 786–3365 (410) 786–2749
XIV Medicare-Approved Eding Volume Reduction Surgery Facilities XIV Medicare-Approved Bariatric Surgery Facilities XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials All Other Information	Sarah Fulton, MHS David Dolan, MBA Annette Brewer	(410) 786–2749 (410) 786–3365 (410) 786–6580

SUPPLEMENTARY INFORMATION:

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) furnishing information to Medicare and Medicaid beneficiaries. health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and "real time" accessibility. In addition, many of the websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website proves to be

difficult, the contact person listed can provide information.

III. How To Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at http://www.cms.gov/manuals.

The Director of the Office of Strategic Operations and Regulatory Affairs of the Centers for Medicare & Medicaid Services (CMS), Kathleen Cantwell, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: November 4, 2022.

Trenesha Fultz-Mimms,

Federal Register Liaison, Department of Health and Human Services.

BILLING CODE 4120-01-P

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: November 18, 2021 (86 FR 64492), February 9, 2022 (87 FR 7458), May 13, 2022 (87 FR 29327) and August 4, 2022 (87 FR 47751). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (July through September 2022)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: http://cms.gov/manuals.

How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at http://www.gpo.gov/libraries/

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government

publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual for Revision to National Coverage Determination (NCD) 240.2 (Home Use of Oxygen) to Align to 1834(a)(5)(E) of the Social Security Act (CMS-Pub. 100-03) Transmittal No. 11587.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual.

Fee-For Service Transmittal Numbers

<u>Please Note</u>: Beginning Friday, March 20, 2020, there will be the following change regarding the Advance Notice of Instructions due to a CMS internal process change. Fee-For Service Transmittal Numbers will no longer be determined by Publication. The Transmittal numbers will be issued by a single numerical sequence beginning with Transmittal Number 10000.

For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

Transmittal Number	Manual/Subject/Publication Number
	Medicare General Information (CMS-Pub. 100-01)
11520	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
11438	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
	Medicare Benefit Policy (CMS-Pub. 100-02)
11501	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11520	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
1	Medicare National Coverage Determination (CMS-Pub. 100-03)
11587	Revision to National Coverage Determination (NCD) 240.2 (Home Use of Oxygen) to Align to 1834(a)(5)(E) of the Social Security Act
	Medicare Claims Processing (CMS-Pub. 100-04)
11484	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11486	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction

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11490 Issued to a specific audience, not posted to Internet/Intra Confidentiality of Instruction 11493 Claim Status Category and Claim Status Codes Update	met due to a
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11493 Claim Status Category and Claim Status Codes Update	
y ,	
11494 Issued to a specific audience, not bosted to internet/intra	
of Instructions	•
11496 October 2022 Quarterly Average Sales Price (ASP) Med	licare Part B Drug
Pricing Files and Revisions to Prior Quarterly Pricing Fil	les
Issued to a specific audience, not posted to Internet/Intra	net due to a
Confidentiality of Instruction	
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11500 Issued to a specific audience, not posted to Internet/Intra	met due to a
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of Instructions	•
11504 Modification of Existing Common Working File (CWF)	Editing for
Preventive Services	
11507 Issued to a specific audience, not posted to Internet/Intra	met due to a
Confidentiality of Instruction	
11508 Issued to a specific audience, not posted to Internet/Intra	inet due to a
Confidentiality of Instruction	
11509 Cessation of Use of MyMedicare.gov Web Address	
11510 Masking the Medicare Beneficiary Identifier (MBI) on the	he Medicare
Summary Notice (MSN)	
11511 Issued to a specific audience, not posted to Internet/Intra	met due to a
Confidentiality of Instruction	
11514 Issued to a specific audience, not posted to Internet/Intra	net due to a
Confidentiality of Instruction	
11518 Issued to a specific audience, not posted to Internet/Intra	met due to Sensitivity
of Instructions	*
11519 Issued to a specific audience, not posted to Internet/Intra	net due to Sensitivity
of Instructions	·
11520 Issued to a specific audience, not posted to Internet/Intra	net due to Sensitivity
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Confidentiality of Instruction	
11527 Issued to a specific audience, not posted to Internet/Intra	met due to a
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Confidentiality of Instruction	
Issued to a specific audience, not posted to Internet/Intra	net due to a
Confidentiality of Instruction	
11540 Inpatient Rehabilitation Facility (IRF) Annual Update: P	Prospective Payment
System (PPS) Pricer Changes for FY 2023	
11541 Medicare Part A Skilled Nursing Facility (SNF) Prospec	tive Payment System
(PPS) Pricer Update Fiscal Year (FY) 2023	
11542 Update to Hospice Payment Rates, Hospice Cap, Hospic	e Wage Index and
Hospice Pricer for Fiscal Year (FY) 2023	
11543 Inpatient Psychiatric Facilities Prospective Payment Syst	tem (IPF PPS)
Updates for Fiscal Year (FY) 2023	
11544 Quarterly Update to the Medicare Physician Fee Schedul	le Database
(MPFSDB) - October 2022 Update	
New Waived Tests	

11548	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11549	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
11551	Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment
11552	Claim Status Category and Claim Status Codes Update
	Issued to a specific audience, not posted to Internet/Intranet due to a
11555	Confidentiality of Instruction
11558	Combined Common Edits/Enhancements Modules (CCEM) Code Set Update
11559	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
11560	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
11561	Implement Operating Rules - Phase III Electronic Remittance Advice (ERA)
11501	Electronic Funds Transfer (EFT): Committee on Operating Rules for
	Information Exchange (CORE) 360 Uniform Use of Claim Adjustment
	Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and
	Claim Adjustment Group Code (CAGC) Rule – Update from Council for
	Affordable
11564	Influenza Vaccine Payment Allowances - Annual Update for 2022-2023
	Season
11565	2023 Annual Update for the Health Professional Shortage Area (HPSA)
	Bonus Payments
11566	January 2023 Healthcare Common Procedure Coding System (HCPCS)
	Quarterly Update Reminder
11567	Annual Clotting Factor Furnishing Fee Update 2023 Updates are Being Mad
	to Chapter 1 of the Medicare Claims Processing Manual to Include Newly
	Created and Utilized Payer Only Codes
11571	Updates are Being Made to Chapter 1 of the Medicare Claims Processing
11371	Manual to Include Newly Created and Utilized Payer Only Codes
11572	Exceptions to Average Sales Price (ASP) Payment Methodology – Claims
113/2	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
11572	Processing Manual Changes 2023 Annual Update of Healthcare Common Procedure Coding System
11573	2023 Annual Opdate of Healthcare Common Procedure Coding System
	(HCPCS) Codes for Skilled Nursing Facility (SNF) Consolidated Billing
	(CB) Update
11581	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
11583	Changes to the Laboratory National Coverage Determination (NCD) Edit
	Software for January 2023
11589	Billing for Hospital Part B Inpatient Services Editing Of Hospital Part B
	Inpatient Services: Reasonable and Necessary Part A Hospital Inpatient
	Denials Editing Of Hospital Part B Inpatient Services: Other Circumstances
	Which Payment Cannot Be Made under Part A
11590	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04,
11370	Chapter 3, Section 20.1.2.7 to Correct the Device Reductions Data Element i
	the FISS Extract File Procedure for Medicare Contractors to Perform and
11591	Record Outlier
11391	Instructions for Retrieving the January 2023 Medicare Physician Fee
	Schedule Database (MPFSDB) Files Through the CMS Mainframe
	Telecommunications System
11592	Issued to a specific audience, not posted to Internet/Intranet due to a
	Sensitivity of Instruction
11593	October 2022 Integrated Outpatient Code Editor (I/OCE) Specifications
	Version 23.3
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	Federal Register/Vol. 87, No. 218/Monday, November 14, 2022/Notices
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	(OPPS)
11505	
11595	Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and
44.500	Laboratory Services Subject to Reasonable Charge Payment
11596	Annual Clotting Factor Furnishing Fee Update 2023
11599	Quarterly Update to the National Correct Coding Initiative (NCCI)
	Procedure-to-Procedure (PTP) Edits, Version 29.0, Effective January 2023
11600	Instructions for Retrieving the January 2023 Opioid Treatment Program
	(OTP) Payment Rates Through the CMS Mainframe Telecommunications
	System
11601	Annual Update of Healthcare Common Procedure Coding System (HCPCS)
	Codes Used for Home Health Consolidated Billing Enforcement
11602	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
11603	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
11604	Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and
	Laboratory Services Subject to Reasonable Charge Payment
11605	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
11610	October 2022 Update of the Ambulatory Surgical Center (ASC) Payment
11010	System
11611	January 2023 Quarterly Average Sales Price (ASP) Medicare Part B Drug
11011	Pricing Files and Revisions to Prior Quarterly Pricing Files
11612	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics,
11012	and Supplies (DMEPOS) Competitive Bidding Program (CBP) - January
	2023
11617	
11617	Instructions for Retrieving the January 2023 Home Infusion Therapy (HIT)
	Services Payment Rates Through the CMS Mainframe Telecommunications
44.40	System
11618	Instructions for Downloading the Medicare ZIP Code File for January 2023
11619	October Quarterly Update for 2022 Durable Medical Equipment, Prosthetics,
	Orthotics and Supplies (DMEPOS) Fee Schedule
11620	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
11621	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
	Medicare Secondary Payer (CMS-Pub. 100-05)
11512	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
11513	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
11550	Significant Updates to Internet Only Manual (IOM) Publication (Pub.) 100-05
	Medicare Secondary Payer (MSP) Manual, Chapter 5
11557	Automation of the Medicare Duplicate Primary Payment (DPP) Process
	Medicare Financial Management (CMS-Pub. 100-06)
11495	Automation of the Duplicate Primary Payer (DPP) Process
11499	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files
	to the Provider and Statistical Reimbursement (PS&R) System
11562	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files
	to the Provider and Statistical Reimbursement (PS&R) System
	Medicare State Operations Manual (CMS-Pub. 100-07)
207	Revisions to State Operation Manual (SOM), Appendix PP Guidance to
207	Surveyors for Long Term Care Facilities
	Medicare Program Integrity (CMS-Pub. 100-08)
	Issued to a specific audience, not posted to Internet/Intranet due to a
11480	Issued to a specific audience, not posted to internet/intranet due to a

	Confidentiality of Instruction
11483	Issued to a specific audience, not posted to Internet/Intranet due to a
11483	Confidentiality of Instruction
11528	Issued to a specific audience, not posted to Internet/Intranet due to a
11328	Confidentiality of Instruction
11529	Update of Chapter 3 in Publication (Pub.) 100-08, Including Update to
11327	Medicare Program Integrity Contractor Post-Payment Review Process, and
	Update of Chapter 8 Pub. 100-08, Including Revision to When Contractor
	Suspects Additional Improper Claims Medical Record Review Contractor
	Suspects Additional Improper Claims
11530	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
11536	Provider/Supplier Enrollment Adverse Legal Actions
11537	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
11556	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
11563	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
11574	Sixth General Update to Provider Enrollment Instructions in Chapter 10 of
	Publication (Pub.) 100-08, Program Integrity Manual (PIM)
11575	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
11576	Final Round of Transition of Enrollment and Certification Activities for
11.500	Various Certified Provider and Supplier Types and Transactions
11580	Issued to a specific audience, not posted to Internet/Intranet due to a
11588	Sensitivity of Instruction Issued to a specific audience, not posted to Internet/Intranet due to
11388	Confidentiality of Instructions
11597	Issued to a specific audience, not posted to Internet/Intranet due to a
11377	Sensitivity of Instruction
11598	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
11606	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
11608	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
11609	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
11613	Final Round of Transition of Enrollment and Certification Activities for
	Various Certified Provider and Supplier Types and Transactions
	Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)
11579	Issued to a specific audience, not posted to Internet/Intranet due to
44.64.6	Confidentiality of Instructions
11616	The Supplemental Security Income (SSI)/Medicare Beneficiary Data for
	Fiscal Years (FYs) 2019 and 2020 for Inpatient Prospective Payment System
*	(IPPS) Hospitals with Updated Data for Hospitals in the 9th Circuit
1	Medicare Quality Improvement Organization (CMS- Pub. 100-10) None
M.J.	None are End Stage Renal Disease Network Organizations (CMS Pub 100-14)
.viedic	None None
X1-1	None None None None
Med	None None
	Medicare Managed Care (CMS-Pub. 100-16)
	None
	TYVIIV

N	Medicare Business Partners Systems Security (CMS-Pub. 100-17)
11570	Pub 100-17 Medicare Business Partners Systems Security Manual Update
	Medicare Prescription Drug Benefit (CMS-Pub. 100-18)
	None
	Demonstrations (CMS-Pub. 100-19)
11489	ESRD Treatment Choices (ETC) Model Performance Payment Adjustment
	(PPA) - Facility Component (Implementation CR)
11505	Concatenation of Multiple Separate Comma-Separated Values Files to One
	File - Update to CR 12492 – Implementation
11506	Issued to a specific audience, not posted to Internet/Intranet due to a
	Sensitivity of Instruction
11515	Federally Qualified Health Center (FQHC) Participation in and Payment
	Under the Maryland Primary Care Program (MDPCP) - Implementation
	Change Request (CR) to correct Business Requirement (BR) 12326.7.2.
11516	Monthly Report of Performance Payment Adjustment (PPA) Claims -
	Addition to Change Request (CR) 12404 - Implementation CR
11517	Remove Beneficiaries Below 18 Years Old From Model Adjustments –
	Correction for CR11390
11534	Issued to a specific audience, not posted to Internet/Intranet due to a
	Sensitivity of Instruction
11553	Automatic Reprocessing of Claims for Kidney Care Choices (KCC) Model-
	Implementation
11554	Issued to a specific audience, not posted to Internet/Intranet due to a
	Sensitivity of Instruction
	One Time Notification (CMS-Pub. 100-20)
11481	Issued to a specific audience, not posted to Internet/Intranet due to a
	Sensitivity of Instruction
11482	Issued to a specific audience, not posted to Internet/Intranet due to a
	Sensitivity of Instruction
11485	Instructions to the Fiscal Intermediary Shared System [FISS] Edit to Expand
	the Existing MA Bypass Reusable Solution PARMCC78 and Modify the
	Existing Logic to Read the New PARMs
11488	New Edit for Prospective Payment System (PPS) Outpatient and Inpatient Bill
	Types Receiving an Outlier Payment When a Device Credit is Reported
11491	Interns and Residents Information System (IRIS) XML Format
11492	User CR: MCS - HIMR Functions Menu Additional Fields
11503	Corrections to Processing of Canceled Home Health Notices of Admission
	and of Period Sequence Edits
11521	Multi-Carrier System (MCS) Removal of the Physician Pay for Reporting
	(P4R), Physician Quality Reporting System (PQRS) and Electronic
	Prescribing (ERx) Incentive Payments Financial Logic from the Claims
	Processing System
11522	Remove Hard Coded Logic for Edits 004H and 005H - Remove the Edits
	from Displaying on the H99RBEA1 and H99RBEA2 Reports
11524	Issued to a specific audience, not posted to Internet/Intranet due to
44.50.5	Confidentiality of Instructions
11525	User Enhancement Change Request (CR) - Update the Multi-Carrier System
	(MCS) Desk Top Tool (MCSDT) Editing for Same Day Adjustments
11526	User Enhancement Change Request (CR)- Update the Model Participant
1	Provider (M1) Screen and Model Participant Provider Report (H99RVMPP)
11500	in the Multi-Carrier System (MCS)
11533	Implementation of the Capital Related Assets Adjustment (CRA) for the
	Transitional Add-on Payment Adjustment for New and Innovative Equipment
1	and Supplies (TPNIES) Under the End Stage Renal Disease Prospective
	Payment System (ESRD PPS)

11535	Health Insurance Portability and Accountability Act (HIPAA) Electronic Data
	Interchange (EDI) Front-End Updates for January 2023
11538	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11539	Implementation of the Award for the Jurisdiction N (J-N) Part A and Part B
11005	Medicare Administrative Contractor (JN A/B MAC)
11545	International Classification of Diseases, 10th Revision (ICD-10) and Other
	Coding Revisions to National Coverage Determination (NCDs)January
	2023 Update
11546	The purpose of this Change Request (CR) is to provide a maintenance update
	of ICD-10 conversions and other coding updates specific to NCDs. These
	NCD coding changes are the result of newly available codes, coding revisions
	to NCDs released separately, or coding feedback received. Previous NCD
	coding changes appear in ICD-10 quarterly updates that can be found at:
	https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/ICD10.html,
	along with other CRs implementing new policy NCDs
11568	User CR: MCS - HIMR Functions Menu Additional Fields
11569	Medicare Summary Notice (MSN) Created with Wrong Beneficiary Data -
	Update Beneficiary Data Streamlining Logic
11577	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
11578	Updated Merit-based Incentive Payment System (MIPS)/MIPS Value
	Pathways (MVP) Healthcare Common Procedure Coding System (HCPCS)
	Codes
11582	Mobile Personal Identity Verification (PIV) Station
11584	International Classification of Diseases, 10th Revision (ICD-10) and Other
	Coding Revisions to National Coverage Determination (NCDs)January
	2023 Update
11585	User Enhancement Change Request (CR) - Update the Multi-Carrier System
	(MCS) Desk Top Tool (MCSDT) Editing for Same Day Adjustments
11586	Issued to a specific audience, not posted to Internet/Intranet due to a
	Sensitivity of Instruction
11607	Issued to a specific audience, not posted to Internet/Intranet due to a
	Sensitivity of Instruction
11614	Issued to a specific audience, not posted to Internet/Intranet due to a
11622	Sensitivity of Instruction
11622	Changes to Beneficiary Coinsurance for Additional Procedures Furnished
	During the Same Clinical Encounter As Certain Colorectal Cancer Screening
11622	Tests Updates to the Common Working File (CWF) for Editing and Claims
11623	Processing to Allow Medicare Fee-For-Service (FFS) Coverage of Kidney
	Acquisition Costs for Medicare Advantage (MA) Beneficiaries Provided by
	Maryland Waiver (MW) Hospitals
May	licare Quality Reporting Incentive Programs (CMS- Pub. 100-22)
, , , , , , , , , , , , , , , , , , , 	None
	State Payment of Medicare Premiums (CMS-Pub.100-24)
	None
Info	rmation Security Acceptable Risk Safeguards (CMS-Pub. 100-25)
11111	None
L	Tione

Addendum II: Regulation Documents Published in the Federal Register (July through September 2022)
Regulations and Notices

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Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register**, contact GPO at www.gpo.gov/fdsys. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through <u>GPO Access</u>. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at http://www.gpoaccess.gov/fr/index.html. The following website http://www.archives.gov/federal-register/ provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our website at: https://www.cms.gov/files/document/regs3q22qpu.pdf

For questions or additional information, contact Terri Plumb (410-786-4481).

Addendum III: CMS Rulings (July through September 2022)

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

Addendum IV: Medicare National Coverage Determinations (July through September 2022)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in

some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. There are no updates to national coverage determinations (NCDs), or reconsiderations of completed NCDs published in the 3-month period. This information is available at: www.cms.gov/medicare-coverage-database/. For questions or additional information, contact Wanda Belle, MPA (410-786-7491).

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (July through September 2022)

(Inclusion of this addenda is under discussion internally.)

Addendum VI: Approval Numbers for Collections of Information (July through September 2022)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact William Parham (410-786-4669).

Addendum VII: Medicare-Approved Carotid Stent Facilities (July through September 2022)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Date Approved	State	
The following facilities are new listings for this quarter.				
Medical City Alliance 3101 N. Tarrant Parkway	670103	05/01/2022	TX	

Facility	Provider	Date	State
Fort Worth, TX 76177	Number	Approved	
South Baldwin Regional Medical	010083	07/07/2022	AL
1613 N. McKenzie Street	010083	07/07/2022	AL
Foley, AL 36535			
Ogden Regional Medical Center	1720031636	07/15/2022	UT
5475 South 500	1,20031030	07/15/2022	
Ogden, UT 844505			
Cleveland Clinic Tradition Hospital	100044	07/26/2022	FL
10000 SW Innovation Way			
Port St. Lucie, FL 34987			
Cleveland Clinic Martin North Hospital	100044	07/26/2022	FL
200 SE Hospital Avenue			
Stuart, FL 34994			
Aurora St. Luke's Medical Center	520138	07/09/2022	WI
2900 West Oklahoma Avenue			
Milwaukee, WI 53215			
HCA Florida Gulf Coast Hospital	1548392475	08/16/2022	FL
449 W. 23rd Street			
Panama City, FL 32405			
Decatur Morgan Hospital	010085	09/20/2022	AL
1201 7th Street			
Decatur, AL 35601			
Centennial Hills Hospital Medical	290054	09/27/2022	NV
Center			
6900 N. Durango Drive			
Las Vegas, NV 89149			
Indiana Regional Medical Center	390173	10/25/2022	PA
835 Hospital Road			
Indiana, PA 15701	250040	10/25/2022	077
Stillwater Medical Center Authority	370049	10/25/2022	OK
1323 W. 6th Avenue			
Stillwater, OK 74074 Memorial Hermann Sugar Land	1295788735	10/25/2022	TX
Hospital	1293/88/33	10/23/2022	
17500 W Grand Parkway S			
Sugar Land, TX 77479			
Hilo Medical Center	120005	10/25/2022	HI
1190 Waianuenue Avenue	120005	10,20,2022	
Hilo, HI 96720			
The following facilities	have editorial ch	anges (in bold).	
FROM: Blake Medical Center	114964244	11/06/2008	FL
TO: HCA Florida Blake Hospital			
2020 59 th Street W			
Bradenton, FL 34209			
FROM: Orlando Health	100006	05/23/2005	FL
TO: OH Orlando Regional Medical			
Center			
1414 Kuhl Avenue			
Orlando FL 32806			
FROM: St. Francis Hospital and	150162	08/28/2006	IN
Health Centers – Indianapolis			
TO: Franciscan Health Indianapolis			[]
8111 South Emerson Avenue			
Indianapolis, IN 46237			

Facility	Provider Number	Date Approved	State
FROM: Great River Medical Center	420680407	04/16/2010	IA
TO: Southeast Iowa Regional			
Medical Center			
1221 S. Gear Avenue			
West Burlington, IA 52655-1681			
The following t	facility is being re	moved.	
Franciscan St. Francis Health -	150033	04/01/2005	IN
Indianapolis			
1600 Albany Street			
Beech Grove, IN 46107			

Addendum VIII:

American College of Cardiology's National Cardiovascular Data Registry Sites (July through September 2022)

The initial data collection requirement through the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) has served to develop and improve the evidence base for the use of ICDs in certain Medicare beneficiaries. The data collection requirement ended with the posting of the final decision memo for Implantable Cardioverter Defibrillators on February 15, 2018.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum IX: Active CMS Coverage-Related Guidance Documents (July through September 2022)

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

Addendum X:

List of Special One-Time Notices Regarding National Coverage Provisions (July through September 2022)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is

available at http://www.cms.gov . For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

Addendum XI: National Oncologic PET Registry (NOPR) (July through September 2022)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron** emission tomography (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA (410-786-3365).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (July through September 2022)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at

http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA, (410-786-3365).

Facility	Provider Number	Date of Initial Certification	Date of Re- certification	State
The following		editorial changes		
Westchester Health Care	330234	11/29/2009	06/30/2022	NY
Corporation				
100 Woods Road				
Valhalla, NY 10595				
Other information:				
Joint Commission ID # 2518				
D : D :: C ::				
Previous Re-certification				
Dates: 11/19/2009; 11/15/2011; 12/03/2013;				
12/08/2015; 12/19/2017;				
03/07/2020				
Ronald Reagan UCLA Medical	050262	02/06/2009	04/09/2022	CA
Center Center	030202	02/00/2009	04/03/2022	CI
757 Westwood Plaza				
Los Angeles, CA 90095				
Other information:				
Joint Commission ID # 9944				
Previous Re-certification				
Dates: 02/06/2009;				
08/09/2011; 08/13/2013;				
09/15/2015; 10/06/2017;				
12/04/2019	0.40007	11/21/2017	05/04/2022	A D
St. Vincent Infirmary Medical Center dba CHI St. Vincent	040007	11/21/2017	05/04/2022	AR
2 St. Vincent Circle				
Little Rock, AR 72205				
Little Rock, AR 72203				
Other information:				
Joint Commission ID # 8661				
Previous Re-certification				
Dates: 11/21/2017; 02/05/2020				
Lancaster General Hospital	390100	05/19/2009	05/04/2022	PA
555 North Duke Street				
Lancaster, PA 17602				
Other information:			1	
Joint Commission ID # 6086				
Previous Re-certification				
Dates: 05/19/2009;				
09/23/2011; 09/06/2013;			1	
09/22/2015; 10/03/2017;				
02/05/2020				
University of Kentucky	180067	02/10/2009	05/12/2022	KY
Hospital/UK Albert B.			1	
Chandler Hospital			1	
800 Rose Street				
Lexington, KY 40536-0293			1	

68170

		1		
Other information:				
Joint Commission ID # 7760				
Previous Re-certification				
Dates: 02/10/2009; 09/20/2011; 09/18/2013;				
11/03/2015; 12/05/2017;				
02/26/2020				
Lehigh Valley Hospital	390133	10/29/2013	05/28/2022	PA
1200 S. Cedar Crest Boulevard				
Allentown, PA 18105				
Other information:				
Joint Commission ID # 4880				
Previous Re-certification				
Dates: 10/29/2013; 11/10/2015; 12/12/2017;				
03/04/2020				
UMC Health System	450686	06/17/2017	07/26/2022	TX
602 Indiana Avenue				
Lubbock, TX 79415				
DNV Healthcare Certificate #:				
C558801				
Previous Re-certification				
Dates: 06/17/2017;				
06/09/2019 West Penn Allegheny Health	390050	03/07/2008	07/27/2022	PA
System, Inc.	390030	03/07/2008	0//2//2022	ГA
320 East North Avenue				
Pittsburgh, PA 15212				
Other information: Joint Commission ID # 6158				
Joint Commission ID # 6138				
Previous Re-certification				
Dates: 03/07/2008;				
04/02/2010; 03/13/2012;				
02/11/2014; 03/15/2016;				
03/30/2018; 01/09/2021 University of Michigan Health	230046	03/27/2008	06/03/2022	MI
System		25.27.2500		
1500 E Medical Center Drive,				
SPC 5474				
Ann Arbor, MI 48109				
Other information:				
Joint Commission ID # 7457				
Previous Re-certification				
Dates: 03/27/2008; 03/18/2010; 03/07/2012;				
02/04/2014; 03/15/2016;				
04/24/2018; 12/03/2020				

Baptist Health Medical Center - Little Rock 9601 Baptist Health Drive Little Rock, AR 72205-7299 Other information:	040114	11/10/2009	05/07/2022	AR
Joint Commission ID # 8656				
Previous Re-certification Dates: 11/10/2009; 11/08/2011; 12/11/2013; 01/12/2016; 12/15/2017; 02/12/2020				
Sutter Medical Center 2825 Capitol Ave Sacramento, CA 95816	050108	10/20/2009	06/16/2022	CA
Other information: Joint Commission ID # 2902				
Previous Re-certification Dates: 10/20/2009; 09/22/2011; 10/17/2013; 10/27/2015; 11/07/2017; 03/04/2020				
WellSpan York Hospital 1001 South George Street York, PA 17405	390046	11/19/2012	06/18/2022	PA
Other information: Joint Commission ID # 6228				
Previous Re-certification Dates: 11/19/2013; 12/15/2015; 01/23/2018; 03/14/2020				
UPMC Presbyterian Shadyside 200 Lothrop Street Pittsburgh, PA 15213	390164	06/10/2008	06/03/2022	PA
Other information: Joint Commission ID # 6169				
Previous Re-certification Dates: 06/10/2008; 05/21/2010; 04/12/2012; 03/25/2014; 04/13/2016; 03/20/2018; 12/09/2020				
NYU Langone Hospitals 550 First Avenue New York, NY 10016	330214	02/14/2012	07/27/2022	NY
Other information: Joint Commission ID # 5820				
Previous Re-certification Dates: 02/14/2012;				

68171

01/14/2014 02/00/2016	1		1	
01/14/2014; 03/08/2016;				
03/27/2018; 8/26/2020				
The Johns Hopkins Hospital	210009	12/11/2007	06/15/2022	MD
600 N. Wolfe Street				
Baltimore, MD 21287				
Other information:				
Joint Commission ID # 6252				
Previous Re-certification				
Dates:				
12/11/2007; 12/15/2009;				
11/29/2011; 12/03/2013;				
01/12/2016; 02/13/2018;				
10/24/2020				
FROM: Jackson Memorial	100022	10/22/2009	06/22/2022	FL
	100022	10/22/2009	06/22/2022	LL
Hospital				
TO: Public Health Trust of				
Dade County Florida dba				
Jackson Memorial Hospital				
1611 Northwest 12th Avenue				
Miami, FL 33136-1094				
Other information:				
Joint Commission ID # 6850				
Previous Re-certification				
Dates:				
10/22/2009; 10/21/2011;				
11/06/2013; 12/08/2015;				
12/08/2017; 3/3/2020				
Christ Hospital	360163	02/17/2012	07/09/2022	ОН
2139 Auburn Avenue	500105	02/1//2012	0770572022	011
Cincinnati, OH 45219				
Cincinnati, 011 43219				
Other information:				
Joint commission ID #: 6987				
Joint commission ID #. 6987				
D : D :: C ::				
Previous Re-certification				
Dates:				
02/17/2012; 02/20/2014;				
04/05/2016; 03/20/2018;				
2/26/21				
MedStar Washington Hospital	090011	04/22/2008	07/08/2022	DC
Center				
110 Irving St, NW				
Washington, DC 20010				
Other information:				
Joint Commission ID # 6308				
Previous Re-certification				
Dates: 04/22/2008;				
04/06/2010; 03/23/2012;				
03/04/2014; 05/03/2016;				
05/22/2018; 12/17/2020				
Penn State Milton S. Hershey	390256	04/01/2008	06/30/2022	PA
Medical Center	333230	1 0 2000	50.50.2022	1
Medical Center	l	l	l	

			1	
500 University Drive				
Hershey, PA 17033				
Joint Commission ID # 6075				
Previous Re-certification				
Dates: 04/01/2008;				
03/24/2010; 03/16/2012;				
The state of the s				
04/08/2014; 06/07/2016;				
05/22/2018; 9/11/2020				
University of Texas Medical	450018	01/31/2012	06/08/2022	TX
Branch				
301 University Boulevard				
Galveston, TX 77555-0518				
_				
Other information:				
Joint commission ID #: 9058				
Previous Re-certification				
Dates: 01/31/2012;				
01/28/2014; 02/23/2016;				
01/30/2018; 10/08/2020				
Abington Memorial Hospital	390231	06/28/2012	07/16/2022	PA
1200 Old York Road				
Abington, PA 19001				
J,				
Other information:				
Joint commission ID #: 6013				
Joint commission 15 #. 0013				
Previous Re-certification				
Dates:				
06/28/2012; 06/03/2014;				
06/28/2016; 05/22/2018				
West Virginia University	510001	07/26/2018	08/17/2022	WV
Hospitals, Inc.				
One Medical Center Drive				
Morgantown, WV 26506				
Other information:				
Joint Commission ID # 6444				
Previous Re-certification				
Dates: 07-26-2018; 02-25-2021	120001	00/02/0010	07/21/2022	60
Medical University of South	420004	09/23/2010	07/21/2022	SC
Carolina Medical Center				
169 Ashley Avenue				
Charleston, SC 29425				
Other information:				
Joint Commission ID # 6584				
Previous Re-certification				
Dates:				
09/23/2010; 09/07/2012;				
· · · · · · · · · · · · · · · · · · ·				
08/05/2014; 09/13/2016;				
09/26/2018; 03/24/2021	450054	12 (07/2011	05/05/5055	TP3.7
Scott & White Memorial	450054	12/07/2011	07/02/2022	TX
Hospital	1			
2401 S 31st St				
2401 S 31st St Temple, TX 76508				

Joint commission ID #: 9241 Previous Re-certification Dates: 12/07/2011; 12/03/2013; 01/12/2016; 12/19/2017; 03/05/2020				
Carolinas Medical Center 1000 Blythe Boulevard Charlotte, NC 28232	340113	05/11/2010	08/03/2022	NC
Other information: Joint Commission ID # 6480 Previous Re-certification Dates: 05/11/2010; 05/11/2012; 04/22/2014; 04/12/2016; 04/24/2018; 12/17/2020				
Saint Luke's Hospital of Kansas City 4401 Wornall Road Kansas City, MO 64111	260138	06/15/2010	08/05/2022	МО
Other information: Joint Commission ID # 8351				
Previous Re-certification Dates: 06/15/2010; 06/06/2012; 05/06/2014; 06/21/2016; 05/08/2018; 02/06/2021				
The University of Kansas Hospital Authority 4000 Cambridge Street Kansas City, KS 66160	170040	03/08/2016	07/20/2022	KS
Other information: Joint Commission ID # 8567 Previous Re-certification Dates: 03/08/2016; 03/06/2018				

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (July through September 2022)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
 - Medicare approved for lung transplants.

Only the first two types are in the list. For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Date of Certification	State
Ohio State University Hospitals	36-0085	10/29/2016	ОН
410 West Tenth Avenue, DN 168			
Columbus, OH 43210			
Other information:			
Joint Commission ID # 7029			
Recertification date: 08/28/2021			
Previous Re-certification Dates: 12/15/2018			
Tammie Hayes, Director, LVRS, 614-293-3629			

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (July through September 2022)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

for bariatric surgery that have been certified by ACS and/or ASMBS in the Medicare-approved facilities that meet CMS' minimum facility standards For www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. questions or additional information, contact Sarah Fulton, MHS 3-month period.

There were no additions, deletions, or editorial changes to

Addendum XV: FDG-PET for Dementia and Neurodegenerative for Dementia and Neurodegenerative Diseases Clinical Trials (July through September 2022) in the 3-month period FDG-PET Diseases Clinical Trials published There were no

For questions or additional information, contact David Dolan, MBA (410www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage. This information is available on our website at

[FR Doc. 2022-24670 Filed 11-10-22; 8:45 am] BILLING CODE 4120-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-2683]

Agency Information Collection Activities: Submission for Office of Management and Budget Review; **Comment Request; Data To Support** Social and Behavioral Research as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. **DATES:** Submit written comments

(including recommendations) on the collection of information by December 14, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://

www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0847. Also include the FDA docket number found in brackets in the heading of this document.

(410-786-2749)

FOR FURTHER INFORMATION CONTACT:

JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

OMB Control Number 0910-0847-Extension

This information collection is intended to support FDA-conducted research. Understanding patients, consumers, and healthcare professionals' perceptions and behaviors plays an important role in improving FDA's regulatory decision-

making processes and communications that affect various stakeholders. FDA uses the following methods to achieve these goals: (1) individual indepth interviews, (2) general public focus group interviews, (3) intercept interviews, (4) self-administered surveys, (5) gatekeeper surveys, and (6) focus group interviews. These methods serve the narrowly defined need for direct and informal opinion on a specific topic and serve as a qualitative and quantitative research tool having two major purposes:

- · Obtaining useful information for the development of variables and measures for formulating the basic objectives of social and behavioral research and
- successfully communicating and addressing behavioral changes with intended audiences to assess the potential effectiveness of FDA communications, behavioral interventions, and other materials.

While FDA will use these methods to test and refine its ideas and help develop communication and behavioral strategies research, the Agency will generally conduct further research before making important decisions (such as adopting new policies and allocating or redirecting significant resources to support these policies).

FDA's Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Office of the

Commissioner, and any other Centers will use this mechanism to test communications and social and behavioral methods about regulated drug products on a variety of subjects related to consumer, patient, or healthcare professional perceptions, beliefs, attitudes, behaviors, and use of drug and biological products and related materials. These subjects include social and behavioral research, decisionmaking processes, and communication and behavioral change strategies.

Annually, FDA projects about 25 social and behavioral studies using the variety of test methods listed in this document. FDA is revising this burden to account for the number of studies we

have received in the last 3 years and to better reflect the scope of the information collection.

In the **Federal Register** of August 10, 2022 (87 FR 48665), FDA published a 60-day notice requesting public comment on the proposed collection of information. Three comments were received. The first comment was not responsive. The second comment requested that participants be informed that participation is voluntary and can withdraw at any time. Prior to beginning the interview and several times throughout, participants are informed that their participation is voluntary and that they can withdraw at any time. We believe no further clarification to the

survey instruments are necessary. The third comment expressed concerns regarding the potential misuse of information from the collection. We have previously outlined the scope and purpose of the information collection, and we do not believe further elaboration is necessary. Further, as outlined in the supporting statement, all information collections must be non-controversial, must not retain Personally Identifiable Information, and "will not be used for substantially informing influential policy decisions."

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN 1

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Interviews and Surveys	109,470	1	109,470	0.25 (15 minutes)	27,368

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, our burden estimate for this information collection reflects an overall increase of 35,886 responses with a corresponding increase of 8,972 hours. We attribute this adjustment to an increase in funding and need to obtain additional information in specific areas, particularly substance abuse (for example, opioids and stimulants) and COVID-19. In addition, we attribute the increase in the number of respondents (from 7,298 to 109,470) and decrease in the number of responses per respondent (from 15 to 1) to an inadvertent administrative error reflected in the 60day notice. These changes, however, do not impact the estimated total annual responses or burden hours.

Dated: November 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.
[FR Doc. 2022–24693 Filed 11–10–22; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-E-2271]

Determination of Regulatory Review Period for Purposes of Patent Extension; PREVYMIS IV Solution, New Drug Application 209940

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for PREVYMIS IV Solution, new drug application (NDA) 209940, and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect must submit either electronic or written comments and ask for a redetermination by January 13, 2023. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 15, 2023. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 13, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered

timely if they are received 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—E—2271 for "Determination of Regulatory Review Period for Purposes of Patent Extension; PREVYMIS IV SOLUTION, New Drug Application 209940." 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, 240–402–7500.

 Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https:// www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts

and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved NDA 209940 for marketing the human drug product, PREVYMIS (letermovir) indicated for prophylaxis of cytomegalovirus (CMV) infections and disease in adult CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant. Subsequent to this approval, the USPTO received a patent term restoration application for PREVYMIS (U.S. Patent No. 8,513,255) from AiCuris Anti-infective Cures GmbH and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated

June 21, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of PREVYMIS IV Solution, NDA 209940, represented a first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for PREVYMIS IV Solution, NDA 209940, is 3,157 days. Of this time, 2,911 days occurred during the testing phase of the regulatory review period, while 246 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective: March 20, 2009. The applicant claims September 21, 2013, is the date the investigational new drug application (IND) became effective. However, FDA's records indicate that the effective date of the first IND received for the active ingredient was March 20, 2009.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act: March 8, 2017. FDA has verified the applicant's claim that the NDA for PREVYMIS IV Solution (NDA 209940) was initially submitted on March 8, 2017.

3. The date the application was approved: November 8, 2017. FDA has verified the applicant's claim that NDA 209940 was approved on November 8, 2017.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 894 days of patent term extension.

Note: We have determined that the regulatory review period for the human drug product, PREVYMIS, approved under NDA 209940, is the same as the regulatory review period determined for the human drug product, PREVYMIS, approved under NDA 209939.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21

CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see DATES), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to https://www.regulations.gov at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852

Dated: November 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy. [FR Doc. 2022–24719 Filed 11–10–22; 8:45 am] BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-2512]

Q5A(R2) Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin; International Council for Harmonisation; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Q5A(R2) Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin." The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), formerly the International Conference on Harmonisation. The draft guidance updates the ICH guidance for industry "Q5A Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin"

issued in September 1998 to reflect advances in scientific knowledge and regulatory expectations. The draft guidance is intended to describe risk-based principles and mitigation strategies to assure the viral safety of biotechnology products, including the data necessary to submit in a marketing application.

DATES: Submit either electronic or written comments on the draft guidance by January 13, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https:// www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA– 2022–D–2512 for "Q5A(R2) Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

 Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https:// www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993—0002, or the Office of Communication, Outreach and Development, Center for

Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993—0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1—800—835—4709 or 240—402—8010. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Kathryn King, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4193, Silver Spring, MD 20993–0002, Kathryn.Kingk@ fda.hhs.gov, 240–402–9634.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, Jill. Adleberg@ fda.hhs.gov, 301–796–5259.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Q5A(R2) Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin." The draft guidance was prepared under the auspices of ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, standardized marketing application submissions, and made many other improvements in the quality of global drug development and manufacturing and the products available to patients.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. Additionally, the Membership of ICH has expanded to

include other regulatory authorities and industry associations from around the world (refer to https://www.ich.org/).

ICH works by involving technical experts from both regulators and industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In September 2022, the ICH Assembly endorsed the draft guideline entitled "Q5A(R2) Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin" and agreed that the guideline should be made available for public comment. The draft guideline is the product of the Quality Expert Working Group of the ICH. Comments about this draft guidance will be considered by FDA and the Quality Expert Working Group.

The draft guidance updates the ICH guidance for industry "Q5A Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin" issued in September 1998 to reflect advances in scientific knowledge and regulatory expectations. Revisions include description of new classes of products; inclusion of new virus detection technologies: clarification of new validation strategies; and considerations specific to new manufacturing approaches, such as continuous manufacturing. The draft guidance is intended to describe riskbased principles and mitigation strategies to assure the viral safety of biotechnology products including the data necessary to submit in a marketing application.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on "Q5A Viral Safety Evaluation of Biotechnology

Products Derived From Cell Lines of Human or Animal Origin." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 210 have been approved under OMB control number 0910-0139. The collections of information in 21 CFR part 312 have been approved under 0910-0014. The collections of information in 21 CFR part 601 have been approved under 0910-0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, or https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

Dated: November 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.
[FR Doc. 2022–24685 Filed 11–10–22; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration [Docket No. FDA-2019-E-2273]

Determination of Regulatory Review Period for Purposes of Patent Extension; PREVYMIS, New Drug Application 209939

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined the regulatory review period for PREVYMIS, new drug application (NDA) 209939, and is publishing this notice of that

determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see SUPPLEMENTARY INFORMATION) are incorrect must submit either electronic or written comments and ask for a redetermination by January 13, 2023. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 15, 2023. See "Petitions" in the SUPPLEMENTARY INFORMATION section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 13, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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—E—2273 for "Determination of Regulatory Review Period for Purposes of Patent Extension; PREVYMIS, New Drug Application 209939". 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, 240–402–7500.

 Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https:// www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved NDA 209939 for marketing the human drug product, PREVYMIS (letermovir). PREVYMIS is indicated for prophylaxis of cytomegalovirus (CMV) infections and disease in adult CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant. Subsequent to this approval, the USPTO received a patent term restoration application for PREVYMIS (U.S. Patent No. RE46791) from AiCuris Antiinfective Cures GmbH, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 21, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of PREVYMIS (NDA 209939) represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for PREVYMIS—RE46791 (NDA 209939) is 3,157 days. Of this time, 2,911 days occurred during the testing phase of the regulatory review period, while 246 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective: March 20, 2009. The applicant claims February 19, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 20, 2009, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act: March 8, 2017. FDA has verified the applicant's claim that NDA 209939 for PREVYMIS was initially submitted on March 8, 2017.

3. The date the application was approved: November 8, 2017. FDA has verified the applicant's claim that NDA 209939 was approved on November 8, 2017.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension for patent number RE46791, this applicant seeks 1,701 days of patent term extension.

Note: We have determined that the regulatory review period for the human drug product, PREVYMIS, approved under NDA 209939 is the same as the regulatory review period determined for

the human drug product, PREVYMIS, approved under NDA 209940.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see DATES). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see DATES), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to https://www.regulations.gov at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.
[FR Doc. 2022–24718 Filed 11–10–22; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration [Docket No. FDA-2021-D-0997]

Referencing the Definition of "Device" in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance entitled "Referencing the Definition of 'Device' in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents." FDA is issuing this guidance to promote clarity regarding references to the terms "device" and "counterfeit device" in guidance, regulatory documents, communications, and other public documents.

DATES: The announcement of the guidance is published in the **Federal Register** on November 14, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https:// www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA– 2021–D–0997 for "Referencing the Definition of 'Device' in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

 Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https:// www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https:// www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the

SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance

document entitled "Referencing the Definition of 'Device' in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents" to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Eli Tomar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5462, Silver Spring, MD 20993-0002, 301-796-0699; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and

Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-

SUPPLEMENTARY INFORMATION:

I. Background

For many years, the definition of "device" has been codified at section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(h)). As a result of the enactment of the Safeguarding Therapeutics Act (Pub. L. 116–304), the definition of "device" was redesignated as subsection (h)(1) and a new definition of "counterfeit device" was codified at subsection (h)(2) of section 201 of the FD&C Act.

FDA is issuing this final guidance to clarify how the Agency intends to interpret existing references to section 201(h) of the FD&C Act and how we intend to reference the definitions of "device" and "counterfeit device" going forward. This guidance is intended to provide clarity on references to the terms "device" and "counterfeit device"—as well as references to section 201(h) of the FD&C Act—in guidance, regulatory documents, and other communications and documents for FDA staff, industry, and other stakeholders. To minimize the potential for miscommunication, FDA also encourage stakeholders, to the extent practicable, to align with the conventions described in the guidance.

A notice of availability of the draft guidance appeared in the Federal Register of December 16, 2021 (86 FR 71507). FDA considered comments received and revised the guidance to improve clarity, including adding

examples of how the policy in the guidance should be applied.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Referencing the Definition of 'Device' in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at https://www.fda.gov/medical-devices/ device-advice-comprehensiveregulatory-assistance/guidancedocuments-medical-devices-andradiation-emitting-products. This guidance document is also available at https://www.regulations.gov, https:// www.fda.gov/regulatory-information/ search-fda-guidance-documents, or https://www.fda.gov/vaccines-bloodbiologics/guidance-complianceregulatory-information-biologics. Persons unable to download an electronic copy of "Referencing the Definition of 'Device' in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 21008 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

FDA concludes that this guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Dated: November 8, 2022.

Lauren K. Roth.

Associate Commissioner for Policy. [FR Doc. 2022-24707 Filed 11-10-22; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Renewal for the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS). **ACTION:** Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act (FACA) and the Public Health Service (PHS) Act, HHS is hereby giving notice that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) has been renewed. The effective date of the charter renewal is November 10, 2022.

FOR FURTHER INFORMATION CONTACT:

Soohyun Kim, Acting Designated Federal Official, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, 18N38A, Rockville, Maryland 20857; 301–594–4202; or *skim@hrsa.gov*.

SUPPLEMENTARY INFORMATION: The ACHDNC provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under section 1111 of the PHS Act (42) U.S.C. 300b-10). The ACHDNC is also governed by the provisions of the FACA, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees. The ACHDNC advises the Secretary on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. The ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, the ACHDNC's recommendations regarding inclusion of additional conditions for screening on the Recommended Uniform Screening Panel, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA pursuant to section 2713 of the PHS Act (42 U.S.C. 300gg-13). Under this provision, nongrandfathered group health plans and

health insurance issuers offering nongrandfathered group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (i.e., policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening. The charter renewal for the ACHDNC was approved on November 4, 2022. The filing date for the ACHDNC charter renewal is November 10, 2022. Renewal of the ACHDNC charter gives authorization for the committee to operate until November 10, 2024.

A copy of the ACHDNC charter is available on the ACHDNC website at https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html. A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is http://www.facadatabase.gov/.

Maria G. Button,

Director, Executive Secretariat.
[FR Doc. 2022–24674 Filed 11–10–22; 8:45 am]
BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel High-End and Shared Instrumentation Grants.

Date: November 15, 2022.

Time: 2:00 p.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Jonathan Arias, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7840, Bethesda, MD 20892, 301–435– 2406 ariasj@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 8, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–24713 Filed 11–10–22; 8:45 am] BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The 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 purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for the treatment of cancer. The outcome of the evaluation will provide information to internal NCI committees that will decide whether NCI should support requests and make available contract resources for development of the potential therapeutic to improve the treatment of various forms of cancer. The research proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposed research projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; OCT2022 Cycle 42 NExT SEP Committee Meeting.

Date: December 7, 2022. Time: 10:00 a.m. to 3:00 p.m. Agenda: To evaluate the NCI Experimental Therapeutics Program Portfolio.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, Room 3A44, Bethesda, Maryland 20892 (WebEx Meeting).

Contact Persons: Barbara Mroczkowski, Ph.D., Executive Secretary, Discovery Experimental Therapeutics Program, National Cancer Institute, NIH, 31 Center Drive, Room 3A44, Bethesda, Maryland 20817, 301–496–4291, mroczkoskib@ mail.nih.gov.

Toby Hecht, Ph.D., Executive Secretary, Development Experimental Therapeutics Program, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 3W110, Rockville, Maryland 20850, 240–276–5683, toby.hecht2@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: November 7, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–24641 Filed 11–10–22; 8:45 am] BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–0361.

Comments are invited on: (a) whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) 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.

Proposed Project: Fast Track Generic Clearance for the Collection of Qualitative Feedback on the Substance Abuse and Mental Health Services Administration (SAMHSA) Service Delivery

Executive Order 12862 directs federal agencies to provide service to the public that matches or exceeds the best service available in the private sector. As outlined in Memorandum M–11–26, the Office of Management and Budget (OMB) worked with agencies to create a Fast Track process to allow agencies to obtain timely feedback on service delivery while ensuring that the information collected is useful and minimally burdensome for the public, as required by the Paperwork Reduction Act of 1995.

This collection of information is necessary to enable SAMHSA to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with SAMHSA's programs. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services.

These collections will allow for ongoing, collaborative and actionable communications between SAMHSA and its customers and stakeholders. They also allow feedback to contribute directly to the improvement of program management. Per Memorandum M-11-26, information collection requests submitted under this Fast Track Generic will be considered approved unless OMB notifies SAMHSA otherwise within five days. Type of respondent; frequency (annual, quarterly, monthly, etc.); and the affected public (individuals, public or private businesses, state or local governments,

A variety of instruments and platforms will be used to collect information from respondents. The annual burden hours requested (87,500) are based on the number of collections we expect to conduct over the requested period for this clearance.

The estimated annual hour burden is as follows:

ESTIMATED ANNUAL REPORTING BURDEN

Type of collection	Number of respondents	Response per respondent	Hours per response	Total hours
In-person surveys, online surveys, telephone surveys, in-person observation/testing, interviews	75,000 10,000	1 1	0.50	37,500 20,000
voice surveys Unspecified collection formats	10,000 25,000	1 1	0.50 1	5,000 25,000
Totals	120,000			87,500

Send comments to Carlos Graham, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57–A, Rockville, Maryland 20857, *OR* email a copy to *carlos.graham@samhsa.hhs.gov*. Written comments should be received by January 13, 2023.

Carlos Graham.

Reports Clearance Officer.

[FR Doc. 2022–24619 Filed 11–10–22; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–0361.

Comments are invited on: (a) whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) 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.

Proposed Project: Voluntary Customer Satisfaction Surveys To Implement Executive Order 12862 in the Substance Abuse and Mental Health Services Administration (SAMHSA)—(OMB No. 0930–0197)—Extension

SAMHSA provides significant services directly to the public, including treatment providers and State substance abuse and mental health agencies, through a range of mechanisms, including publications, training, meetings, technical assistance and websites. Many of these services are focused on information dissemination activities. The purpose of this submission is to extend the existing generic approval for such surveys.

The primary use for information gathered is to identify strengths and weaknesses in current service provisions by SAMHSA and to make improvements that are practical and feasible. Several of the customer satisfaction surveys expected to be implemented under this approval will provide data for measurement of program effectiveness under the Government Performance and Results Act. Information from these customer surveys will be used to plan and redirect resources and efforts to improve or maintain a high quality of service to health care providers and members of the public. Focus groups may be used to develop the survey questionnaire in some instances.

The estimated annual hour burden is as follows:

Type of data collection	Number of respondents	Responses/ respondent	Hours/ response	Total hours
Focus groups	250 89,750	1 1	2.50 .250	625 22,438
Total	90,000			23,063

Send comments to Carlos Graham, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57–A, Rockville, Maryland 20857, *OR* email a copy to *carlos.graham@samhsa.hhs.gov*. Written comments should be received by January 13, 2023.

Carlos Graham,

Reports Clearance Officer.

[FR Doc. 2022–24618 Filed 11–10–22; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA)

will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276– 0361.

Comments are invited on: (a) whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) 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.

Proposed Project: SAMHSA's Publications and Digital Products Website Registration Survey (OMB No. 0930–0313)—Revision

The Substance Abuse and Mental Health Services Administration

(SAMHSA) is requesting OMB approval for a revision of SAMHSA's **Publications and Digital Products** website Registration Survey (OMB No. 0930-0313). SAMHSA is authorized under section 501(d)(16) of the Public Health Service Act (42 U.S.C. 290aa(d)(16)) to develop and distribute materials for the prevention, treatment, and recovery from mental and substance use disorders. To improve customer service and lessen the burden on the public to locate and obtain these materials, SAMHSA has developed a website that includes more than 500 free publications from SAMHSA and its component Agencies. These products are available to the public for ordering and download. When a member of the public chooses to order hard-copy publications, it is necessary for SAMHSA to collect certain customer information in order to fulfill the request. To further lessen the burden on the public and provide the level of customer service that the public has come to expect from product websites, SAMHSA has developed a voluntary registration process for its publication website that allows customers to create

accounts. Through these accounts, SAMHSA customers are able to access their order histories and save their shipping addresses. During the website registration process, SAMHSA will also ask customers to provide optional demographic information that helps SAMHSA to evaluate the use and distribution of its publications and improve services to the public.

SAMHSA is employing a web-based form for information collection to avoid

duplication and unnecessary burden on customers who register for an account. Customer information is submitted electronically via web forms on the samhsa.gov domain. Customers can submit the web forms at their leisure, or call SAMHSA's toll-free Call Center and an information specialist will submit the forms on their behalf. The electronic collection of information reduces the burden on the respondent and streamlines the data-capturing process.

The following revisions were made to the SAMHSA Publications and Digital Products website Registration Survey:

- Revision of the SAMHSA Publications website Registration Survey Questions.
- Addition of a SAMHSA Main Site Survey version.
- Addition of a SAMHSA Store Survey version.

SAMHSA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Website Registration Survey	21,082	1	21,082	.033 (2 min.)	696

Send comments to Carlos Graham, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57–A, Rockville, Maryland 20857, *OR* email a copy to *carlos.graham@samhsa.hhs.gov*. Written comments should be received by January 13, 2023.

Carlos Graham,

Reports Clearance Officer.
[FR Doc. 2022–24617 Filed 11–10–22; 8:45 am]
BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–0361.

Comments are invited on: (a) whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) 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.

Proposed Project: SAMHSA SOAR Web-Based Data Form (OMB No. 0930– 0329)—Revision

In 2009 the SAMHSA created a Technical Assistance Center to assist in the implementation of the Supplemental Security Income (SSI)/Social Security Disability Insurance (SSDI) Outreach, Access, and Recovery (SOAR) effort in all states. The primary objective of SOAR is to improve the allowance rate for the Social Security Administration's (SSA) disability benefits for people who are experiencing or at risk of homelessness, and who have serious mental illnesses.

During the SOAR training, the importance of keeping track of SSI/SSDI applications through the process is stressed. In response to requests from states implementing SOAR, the Technical Assistance Center under SAMHSA's direction developed a webbased data form that case workers can use to track the progress of submitted applications, including decisions received from SSA either on initial application or on appeal. This password-protected web-based data form is hosted on the SOAR Online Application Tracking (OAT) website (https://soartrack.samhsa.gov). Use of this form is completely voluntary.

There are two parts to the SOAR Webbased Data Form. Part I of the SOAR Web-based Data Form is intended for SOAR-trained case workers to enter the outcomes of SOAR-assisted SSI/SSDI applications. Part II of the SOAR Webbased Data Form includes two sections

reserved for SOAR State Team Leads to report annually. The first section of Part II collects quantitative summary data from states that do not track SOAR-assisted SSI/SSDI applications using the SOAR Web-based Data Form Part I. The second section of Part II collects qualitative (open-ended) questions on annual SOAR accomplishments, identified challenges, and collaborations.

Data from Part I of the SOAR Webbased Data Form can be compiled into reports on decision results and the use of SOAR critical components, such as the SSA–1696 Appointment of Representative, which allows SSA to communicate directly with the case worker assisting with the application. These reports will be reviewed by agency directors, SOAR state-level leads, and the SAMHSA SOAR Technical Assistance Center to quantify the success of the effort overall and to identify areas where additional technical assistance is needed.

There are four proposed changes to Part I of this form. Four additional demographic questions will be asked in Demographic section of the SOAR Data Form Part I to include race, ethnicity, gender, and expanded response options re: involvement in the criminal justice or legal system. These questions will be answered by all 700 case worker respondents, on average 3 times per year. There are two proposed changes to Part II. Two additional response options were added into the Collaborations section of the Qualitative Questionnaire to provide respondents the opportunity to describe collaborations with childserving organizations along with whether meetings and trainings were for SOAR for Adults or SOAR for Children. These questions will be answered by 75 respondents once per year.

The estimated response burden is as follows:

Form name	Numbers of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
SOAR Web-based Data Form (Part I)	700 75	3 1	2,100 75	.25 1	525 37.50
Total	775		2,175		562.50

Send comments to Carlos Graham, SAMHSA Reports Clearance Officer, Room 15E–57A, 5600 Fishers Lane, Rockville, MD 20857 *OR* email him a copy at *Carlos.Graham@ samhsa.hhs.gov*. Written comments should be received by January 13, 2023.

Carlos Graham,

Reports Clearance Officer. [FR Doc. 2022–24616 Filed 11–10–22; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Intent To Request an Extension From OMB of One Current Public Collection of Information: Cybersecurity Measures for Surface Modes

AGENCY: Transportation Security Administration, DHS. **ACTION:** 60-Day notice.

SUMMARY: The Transportation Security Administration (TSA) invites public comment on one currently-approved Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0074, abstracted below, that we will submit to OMB for an extension in compliance with the Paperwork Reduction Act (PRA). On October 26, 2022, OMB approved TSA's request for an emergency approval of this collection to address the ongoing cybersecurity threat to surface transportation and associated infrastructure. TSA is now seeking to renew the collection, which expires on April 30, 2023, with incorporation of the subject of the emergency request. The ICR describes the nature of the information collection and its expected burden. The collection allows TSA to address the ongoing cybersecurity threat to surface transportation systems and associated infrastructure.

DATES: Send your comments by January 13, 2023.

ADDRESSES: Comments may be emailed to *TSAPRA@tsa.dhs.gov* or delivered to the TSA PRA Officer, Information

Technology (IT), TSA-11, Transportation Security Administration, 6595 Springfield Center Drive, Springfield, VA 20598-6011.

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh at the above address, or by telephone (571) 227–2062.

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation will be available at http://www.reginfo.gov upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

- (1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (2) Evaluate the accuracy of the agency's estimate of the burden;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

OMB Control Number 1652–0074; Cybersecurity Measures for Surface Modes. TSA is specifically empowered to assess threats to transportation; ¹ develop policies, strategies, and plans for dealing with threats to transportation; ² oversee the implementation and adequacy of security measures at transportation facilities; ³ and carry out other appropriate duties relating to transportation security.⁴ Additionally, under 49 U.S.C. § 114(*I*)(2),⁵ TSA has the authority to issue Security Directives (SDs) if the Administrator of TSA determines that a regulation or SD must be issued immediately in order to protect transportation security.

On November 30, 2021, OMB approved TSA's request for an emergency approval of this information collection to address the ongoing cybersecurity threat to surface transportation and associated infrastructure. On April 7, 2022, TSA submitted an extension request to OMB, which was approved on October 25, 2022. See ICR Reference Number 202203-1652-003. On October 26, 2022, OMB approved TSA's request for an additional emergency approval, revising this information collection. See ICR Reference Number: 202210-1652-001. The collection covers both mandatory reporting and voluntary reporting of information. The OMB approval allowed for the additional institution of mandatory reporting requirements and collection of information voluntarily submitted. See ICR Reference Number: 202111–1652–003. TSA is now seeking renewal of this information collection for the maximum three-year approval period.

The request for a revised collection was necessary as a result of actions TSA took to address the ongoing cybersecurity threats to the United States' national and economic security posed by this threat to surface transportation and associated infrastructure. On October 18, 2022, TSA issued SD 1580/1582–2022–01 Rail Cybersecurity Mitigation Actions, Contingency Planning, and Testing, which applies to Owner/Operators including the "Higher Risk" freight

¹⁴⁹ U.S.C. 114(f)(2).

^{2 49} U.S.C. 114(f)(3).

^{3 49} U.S.C. 114(f)(11).

⁴⁴⁹ U.S.C. 114(f)(15).

⁵ Notwithstanding any other provision of law or executive order (including an executive order requiring a cost-benefit analysis), if the Administrator determines that a regulation or security directive must be issued immediately in order to protect transportation security, the Administrator shall issue the regulation or security directive without providing notice or an opportunity for comment and without prior approval of the Secretary.

railroads identified in 49 CFR 1580.101 and additional TSA-designated freight and passenger railroads. This SD became effective on October 24, 2022. The emergency request did not affect the previously-approved collection for SD 1580-21-01 and SD 1582-21-01. which remain in effect, mandating TSAspecified Owner/Operators of "higher risk" railroads and rail transit systems, respectively, to implement an array of cybersecurity measures to prevent disruption and degradation to their infrastructure.⁶ The scope of these SDs align with the railroads and rail transit systems required to report significant security incidents to TSA under 49 CFR 1570 203

In addition, the emergency request did not affect the previously-issued "information circular" (IC), which remain in effect. The IC contains non-binding recommendations with the same measures for railroad Owner/ Operators, public transportation agencies, rail transit system Owner/ Operators, and certain over-the-road bus Owner/Operators not specifically covered under SDs 1580–21–01 or 1582–21–01.

The requirements in the SDs and the recommendations in the IC allow TSA to execute its security responsibilities within the surface transportation industry, through awareness of potential security incidents and suspicious activities. TSA plans to collect the following information:

A. SD 1580/82-2022-01 includes the following requirements:

- 1. The Cybersecurity Implementation Plan submitted to TSA for approval that addresses how the Owner/Operator will achieve each of the following prescribed objectives in the SD:
- identification of the Owner/ Operator's Critical Cyber Systems;
- implementation of network segmentation policies and controls to ensure that the Operational Technology system can continue to safely operate in the event that an Information Technology system has been compromised;
- implementation of access control measures to secure and prevent unauthorized access to critical cyber systems;

- implementation of continuous monitoring and detection policies and procedures to detect cybersecurity threats and correct anomalies that affect Critical Cyber System operations; and;
- reduction of the risk of exploitation of unpatched systems through the application of security patches and updates for operating systems, applications, drivers and firmware on Critical Cyber Systems in a timely manner using a risk-based methodology.
- 2. The Annual Audit Plan for the Cybersecurity Assessment Program that describes how the Owner/Operator will proactively and regularly assess the effectiveness of cybersecurity measures, and identify and resolve device, network, and/or system vulnerabilities.
- 3. Provide documentation as necessary to establish compliance, to be provided upon TSA request.
- B. SD 1580-21-01, SD 1582-21-01, and IC 2021-01 remain in effect and include the following information collection requirements for the SDs and recommendations for the IC:
- 1. Designate a Cybersecurity Coordinator who is available to TSA 24/7 to coordinate cybersecurity practices and address any incidents that arise.
- 2. Report cybersecurity incidents to the Cybersecurity and Infrastructure Security Agency (CISA).
- 3. Develop a cybersecurity incident response plan.
- 4. Complete a cybersecurity vulnerability assessment to address cybersecurity gaps using the form provided by TSA.

TSA, in conjunction with federal partners such as CISA, will use the reports of cybersecurity incidents to evaluate and respond to imminent and evolving cybersecurity incidents and threats as they occur, and as a basis for creating new cybersecurity policy moving forward. This monitoring will allow TSA and federal partners to take action to contain threats, take mitigating action, and issue timely warnings to similarly-situated entities against further spread of the threat. TSA and its federal partners will also use the information to inform timely modifications to cybersecurity requirements to improve transportation security and national economic security. TSA will use the collection of information to ensure compliance with TSA's cybersecurity measures required by the SDs and the recommendations under the IC.

Certification of Completion of SD Requirements

The SDs and IC took effect on October 24, 2022. Within 7 days of the effective

date of the SDs, Owner/Operators must provide their designated Cybersecurity Coordinator information: within 90 days of the effective date of the SDs, Owner/ Operators must submit their Cybersecurity Implementation Plan; within 120 days of the effective date of the SDs, Owner/Operators must complete the Vulnerability Assessment (TSA form); within 180 days of the effective date of the SDs, Owner/ Operators must adopt a Cybersecurity Incident Response Plan; and within 7 days of completing the Cybersecurity Incident Response Plan requirement, Owner/Operators must submit a statement to TSA via email certifying that the Owner/Operator has completed this requirement. Owner/Operators can complete and submit the required information via email or other electronic options provided by TSA. Documentation of compliance must be provided upon request. As the measures

provided upon request. As the measures in the IC are voluntary, the IC does not require Owner/Operators to report on their compliance.

Portions of the responses that are

Portions of the responses that are deemed Sensitive Security Information (SSI) are protected in accordance with procedures meeting the transmission, handling, and storage requirements of SSI set forth in 49 CFR part 1520.⁷

TSA estimates SD 1580/82–2022–01 applies to a total of 73 Owner/ Operators; and SD 1580–21–01, SD 1582–21–01, and IC 2021–01 apply to 457 railroad Owner/Operators, 115 public transportation agencies and rail transit system Owner/Operators, and 209 over-the-road bus Owner/Operators, for a total of 781 respondents. For this collection, TSA estimates the total annual respondents to be 854 and the total annual hour burden to be 134,023 hours.

Dated: November 7, 2022.

Christina A. Walsh,

TSA Paperwork Reduction Act Officer, Information Technology.

[FR Doc. 2022–24621 Filed 11–10–22; 8:45 am]

BILLING CODE 9110-05-P

⁶Companies and agencies that are identified as higher-risk service the regions with the highest surface transportation-specific risk. Risk ranking is based on considerations related to ridership, location of services provided (use of the same stations and stops), and relationship between feeder and primary systems. See https://www.tsa.gov/sites/default/files/guidance-docs/high_threat_urban_area_htua_group_designations_0.pdf

⁷In addition, all data in TSA systems are statutorily required to comply with the Federal Information Security Modernization Act 2014 (FISMA) following the National Institute of Standards and Technology Special Publication 800.37 REV2 or Risk Management Framework, and other federal information security requirements including Federal Information Processing Standards 199 and Executive Order 14028. All systems, networks, servers, clouds and endpoints under the FISMA boundary are hardened to meet the Department of Defense Security Technical Implementation Guidelines, as well as DHS Policy (4300.A) and TSA policy (TSA IA Handbook).

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVS00000.L51010000.ER0000. LVRWF2208330.22X; N-89655; MO# 4500164258]

Notice of Intent To Amend the Las Vegas Resource Management Plan and Prepare an Environmental Impact Statement for the Proposed Copper Rays Solar Project in Nye County, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM) Nevada State Director intends to prepare a Resource Management Plan (RMP) amendment with an associated Environmental Impact Statement (EIS) for the Copper Rays Solar Project and by this notice is announcing the beginning of the scoping period to solicit public comments and identify issues, and is providing the planning criteria for public review.

DATES: The BLM requests the public submit comments concerning the scope of the analysis, potential alternatives, and identification of relevant information and studies by December 29, 2022. To afford the BLM the opportunity to consider issues raised by commenters in the Draft RMP amendment/EIS, please ensure your comments are received prior to the close of the 45-day scoping period or 15 days after the last public meeting, whichever is later.

The BLM will conduct two public scoping meetings (virtually):

- December 6, 2022, 6–8 p.m. Pacific Time., Virtual via Zoom. Registration is required. To register in advance for this webinar, visit: https:// eplanning.blm.gov/eplanning-ui/ project/2019523/510
- December 7, 2022, 6–8 p.m. Pacific Time., Virtual via Zoom. Registration is required. To register in advance for this webinar, visit: https:// eplanning.blm.gov/eplanning-ui/ project/2019523/510

ADDRESSES: You may submit comments on issues and planning criteria related to the Copper Rays Solar Project by any of the following methods:

- Website: https://eplanning.blm.gov/ eplanning-ui/project/2019523/510
- Émail: BĽM_NV_SND_ EnergyProjects@blm.gov

 Mail: BLM, Pahrump Field Office, Attn: Copper Rays Solar Project, 4701 North Torrey Pines Drive, Las Vegas, NV 89130–2301

Documents pertinent to this proposal may be examined online at the project ePlanning page: https://eplanning.blm.gov/eplanning-ui/project/2019523/510 and at the Southern Nevada District Office.

FOR FURTHER INFORMATION CONTACT: Whitney Wirthlin, Project Manager, telephone (725) 249-3318; address 4701 North Torrey Pines Drive, Las Vegas, NV 89130–2301; email BLM_NV_SND_ EnergyProjects@blm.gov. Contact Whitney Wirthlin to have your name added to our mailing list. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Whitney Wirthlin. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-ofcontact in the United States.

SUPPLEMENTARY INFORMATION: This document provides notice that the BLM Nevada State Director intends to prepare an RMP amendment with an associated EIS for the Copper Rays Solar Project, announces the beginning of the scoping process, and seeks public input on issues and planning criteria. The RMP amendment is being considered to allow the BLM to evaluate the Copper Rays Solar Project, which would require amending the existing 1998 Las Vegas RMP.

The proposed project and planning area is in Nye County, southeast of the Town of Pahrump and approximately 40 miles west of Las Vegas, and encompasses approximately 5,127 acres of public lands.

On October 27, 2020, Copper Rays Solar, LLC filed an updated right-of-way application to the BLM Pahrump Field Office for the Copper Rays Solar Project (Project) requesting authorization to construct, operate, maintain, and eventually decommission a 700megawatt photovoltaic solar electric generating facility, battery storage facilities, associated generation tie-line, and access road facilities. Copper Rays Solar, LLC submitted the initial right-ofway application for the proposed project in September 2010, thus the project is not subject to the decisions adopted by the Record of Decision for Solar Energy Development in Six Southwestern States (BLM 2012). The electricity generated would be collected at the onsite substation and conveyed to the

Gamebird Substation located north of the project site via transmission line. Construction for the facilities is estimated to take approximately 72 months across multiple phases. The lands within the proposed project area were segregated, subject to valid existing rights, for a term of two years beginning October 21, 2021, with publication of the Notice of Segregation in the **Federal Register**.

The scope of this land use planning process does not include addressing the evaluation or designation of areas of critical environmental concern (ACEC) and the BLM is not considering ACEC nominations as part of this process.

Purpose and Need

The BLM's preliminary purpose and need for this Federal action is to respond to FLPMA right-of-way applications submitted by Copper Rays Solar, LLC under Title V of FLPMA (43 U.S.C. 1761) to construct, operate, maintain, and decommission a solar generation power plant and ancillary facilities on approximately 5,127 acres of BLM land in Nye County, Nevada, in compliance with FLPMA, BLM right-ofway regulations, the BLM NEPA Handbook (BLM 2008), U.S. Department of the Interior NEPA regulations, and other applicable federal and state laws and policies. In accordance with FLPMA, public lands are to be managed for multiple uses that consider the longterm needs of future generations for renewable and non-renewable resources. The BLM is authorized to grant rights-of-way on public lands for systems of generation, transmission, and distribution of electrical energy (Section 501(a)(4)). The preliminary purpose and need also includes an amendment to the 1998 Las Vegas RMP to address utility corridor modifications based on the project boundary location and to adjust the Visual Resource Management Class III unit that contains the proposed project to respond to the proponent's application.

Preliminary Alternatives

The Proposed Action is to approve a right-of-way to Copper Rays Solar, LLC to construct, operate, and eventually decommission the proposed solar project and associated facilities with the potential to generate 700-megawatts of alternating current energy on 5,127 acres of BLM administered lands. The Proposed Action also includes an amendment to the 1998 Las Vegas RMP in order to modify multiple utility corridors and to adjust the Visual Resource Management Class III unit that contains the proposed project.

An Energy Policy Act of 2005 Section 368 Energy Corridor, Segment # 224–225, intersects the western portion of the project area. A Southern Nevada District Utility Corridor, established by the RMP, intersects the southwest corner of the project area. Per the BLM's Land Use Planning Handbook (H–1601–1 Section VII.B), in order for the project to be consistent with the RMP, a plan amendment to modify both utility corridors outside of the Copper Rays Solar Project area will be required.

The Visual Resource Management Class for the project area includes Class III, which requires a RMP amendment to change the Class III area to Class IV in order for the project to be consistent with the RMP, per the BLM Land Use Planning Handbook (H–1601–1 Section VII.B).

Additional action alternatives have not been identified to date but would be developed by taking into consideration comments and input submitted during the application evaluation determination process and scoping.

Under the No Action Alternative, BLM would not issue a right-of-way grant for the solar project and associated facilities. The proposed Project would not be constructed, and existing land uses in the project area would continue. Additionally, the BLM would not undertake a RMP amendment to adjust utility corridors and modify the Visual Resource Management Class.

The BLM welcomes comments on all preliminary alternatives as well as suggestions for additional alternatives.

Planning Criteria

The planning criteria guide the planning effort and lay the groundwork for effects analysis by identifying the preliminary issues and their analytical frameworks. Preliminary issues for the planning area have been identified by BLM personnel and from early engagement conducted for this planning effort with Federal, State, and local agencies; Tribes; and other stakeholders. The BLM has identified preliminary issues for this planning effort's analysis. The planning criteria are available for public review and comment at the ePlanning website (see ADDRESSES).

Summary of Expected Impacts

The analysis in the EIS will be focused on the proposed solar project and associated facilities, including battery storage and transmission line construction. The BLM evaluated the proposed Project application per the 43 CFR 2800 application evaluation determination process. Through this process, the BLM completed public outreach and Agency and Indian Tribal

Nations coordination specific to the proposed Project. From the input received, the expected impacts from construction, operation, and eventual decommissioning of the solar project, associated facilities, and the RMP amendment could include:

- Potential desert tortoise habitat disturbance and changes in genetic connectivity habitat from construction of the proposed facilities;
- Potential effects to cultural resources in the project area from construction activities;
- Potential modifications to the visual character of the area;
- Potential effects to basin groundwater resources from the proposed construction water needs for the project;
- Potential socioeconomic impacts from the proposed project to local communities;
- Potential air quality impacts from proposed construction activities;
- Potential impacts to vegetation species as a result of construction, operations, and decommissioning of the project and associated facilities;
- Potential effects to the recreational opportunities and public use of the proposed project area due to construction and operations of the solar facility; and
- Potential cumulative effects with other reasonably foreseeable actions in the area.

Preliminary issues for the project have been identified by the BLM, other Federal agencies, the State, local agencies, Tribes, and the public during the application evaluation process. The following may be impacted by the proposed project and will be considered for detailed analysis in the EIS: threatened and endangered species, biological resources, vegetation resources, visual resources, cultural resources, air quality, climate change, recreation, socioeconomics, water resources, and cumulative effects from reasonably foreseeable actions in the area. Habitat for the federally listed desert tortoise is in this project area.

Anticipated Permits and Authorizations

Along with the right-of-way grant issued by the BLM, Copper Rays Solar, LLC anticipates needing the following authorizations and permits for the proposed project: Biological Opinion and Incidental Take Permit from the U.S. Fish and Wildlife Service; Consultation under Section 106 of the National Historic Preservation Act with the Advisory Council on Historic Preservation and Nevada State Historic Preservation Office; Section 404 Permit from the U.S. Army Corps of Engineers;

Wildlife Special Purpose permit from the Nevada Department of Wildlife; Nevada Division of Environmental Protection Stormwater and Groundwater Discharge permits and Temporary in Waterways Work permit; Nevada Public **Utilities Commission Permit to** Construct; Nevada Division of Water Resources water rights modification permits; Nevada State Fire Marshall Hazardous Materials Storage permit; Nye County Special Use Permit; and other Nye County permits, as necessary. Further details on these permitting requirements may be found in the Plan of Development for the Copper Rays Solar Project.

Schedule for the Decision-Making Process

The BLM will provide additional opportunities for public participation consistent with the NEPA and land use planning processes, including a 90-day comment period on the Draft RMP Amendment/EIS and concurrent 30-day public protest period and 60-day Governor's consistency review on the Proposed RMP Amendment. The Draft RMP Amendment/EIS is anticipated to be available for public review Spring 2023 and the Proposed RMP Amendment is anticipated to be available for public protest in Fall 2023 with an Approved RMP Amendment and Record of Decision in Spring 2024.

Public Scoping Process

This notice of intent initiates the scoping period and public review of the planning criteria, which guide the development and analysis of the Draft RMP Amendment/EIS.

The BLM will be holding two virtual scoping meetings (see **DATES** and **ADDRESSES** sections earlier). The specific date(s) and location(s) of any additional scoping meetings will be announced at least 15 days in advance through the project ePlanning web page: https://eplanning.blm.gov/eplanning-ui/project/2019523/510.

The purpose of the public scoping process is to determine relevant issues that will influence the scope of the environmental analysis, including alternatives and mitigation measures, and to guide the process for developing the EIS. Federal, State, and local agencies and Tribes, along with other stakeholders that may be interested or affected by the BLM's decision on this project, are invited to participate in the scoping process and, if eligible, may request or be requested by the BLM to participate as a cooperating agency. The BLM encourages comments concerning the proposed Cooper Rays Solar Project and RMP amendment, possible

measures to minimize and/or avoid adverse environmental impacts, and any other information relevant to the Proposed Action.

The BLM also requests assistance with identifying potential alternatives to the Proposed Action. As alternatives should resolve an issue with the Proposed Action, please indicate the purpose of the suggested alternative. In addition, the BLM requests the identification of potential issues that should be analyzed. Issues should be a result of the Proposed Action or Alternatives; therefore, please identify the activity along with the potential issues

Lead and Cooperating Agencies

The BLM Pahrump Field Office is the lead agency for this EIS and RMP amendment. The BLM has initially invited 27 Agencies and 15 Indian Tribal Nations to be cooperating agencies to participate in the environmental analysis of the Project.

Of those invited, 11 agencies have accepted cooperating agency status: U.S. Fish and Wildlife Service Ecological Services Program, U.S. Fish and Wildlife Migratory Bird Program; U.S. Environmental Protection Agency Region 9; Clark County Department of Aviation; Clark County Department of Environment and Sustainability; Nye County; Nevada Department of Wildlife; Nevada Division of Forestry; Nevada Department of Conservation and Natural Resources, Off-Highway Vehicles Program; Nevada Division of Emergency Management; and Nevada Department of Public Safety. Additional agencies and organizations may be identified as potential cooperating agencies to participate in the environmental analysis of the Project.

Responsible Official

The Nevada State Director is the deciding official for this planning effort and proposed Copper Rays Solar Project.

Nature of Decision To Be Made

The nature of the decision to be made will be the State Director's selection of land use planning decisions for managing BLM-administered lands under the principles of multiple use and sustained yield in a manner that best addresses the purpose and need.

The BLM will decide whether to grant, grant with conditions, or deny the right of way application. Pursuant to 43 CFR 2805.10, if the BLM issues right-of-way grant(s), the BLM decision maker may include terms, conditions, and stipulations determined to be in the public interest.

Interdisciplinary Team

The BLM will use an interdisciplinary approach to develop the EIS/RMP amendment in order to consider the variety of resource issues and concerns identified. Specialists with expertise in the following disciplines will be involved in this process: air quality, archaeology, botany, climate change (greenhouse gases), environmental justice, fire and fuels, geology/mineral resources, hazardous materials. hydrology, invasive/non-native species, lands and realty, National Conservation Lands, National Trails, public health and safety, recreation/transportation, socioeconomics, soils, visual resources, and wildlife.

Additional Information

The BLM will identify, analyze, and consider mitigation to address the reasonably foreseeable impacts to resources from the proposed plan amendment and all analyzed reasonable alternatives and, in accordance with 40 CFR 1502.14(e), include appropriate mitigation measures not already included in the proposed plan amendment or alternatives. Mitigation may include avoidance, minimization, rectification, reduction or elimination over time, and compensation; and may be considered at multiple scales, including the landscape scale.

The BLM will utilize and coordinate the NEPA and land use planning processes for this planning effort to help support compliance with applicable procedural requirements under the Endangered Species Act (16 U.S.C. 1536) and Section 106 of the National Historic Preservation Act (54 U.S.C. 306108) as provided in 36 CFR 800.2(d)(3), including public involvement requirements of Section 106. The information about historic and cultural resources and threatened and endangered species within the area potentially affected by the proposed plan amendment will assist the BLM in identifying and evaluating impacts to such resources.

The BLM will consult with Tribal Nations on a government-to-government basis in accordance with Executive Order 13175, BLM MS 1780, and other policies. Tribal concerns, including impacts on Indian trust assets and potential impacts to cultural resources, will be given due consideration. Federal, State, and local agencies, along with Tribal Nations, and other stakeholders that may be interested in or affected by the proposed action that the BLM is evaluating, are invited to participate in the scoping process and, if eligible, may request or be requested

by the BLM to participate in the development of the environmental analysis as a cooperating agency. The BLM intends to hold a series of government-to-government consultation meetings. The BLM will send invites to potentially affected Tribal Nations prior to the meetings. The BLM will provide additional opportunities for government-to-government consultation during the NEPA process.

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.

(Authority: 40 CFR 1501.7, 43 CFR 1610.2, and 2800)

Jon Raby,

State Director.

[FR Doc. 2022–24623 Filed 11–10–22; 8:45 am] BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[L14400000 PN0000 HQ350000 212; OMB Control No. 1004-0119]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Permits for Recreation on Public Land

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Land Management (BLM) proposes to renew an information collection.

DATES: Interested persons are invited to submit comments on or before December 14, 2022.

ADDRESSES: Written comments and recommendations for this information collection request (ICR) should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request additional information about

this ICR, contact KC Craven by email at kcraven@blm.gov, or by telephone at (702) 515–5374. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at http://www.reginfo.gov/public/do/PRAMain.

SUPPLEMENTARY INFORMATION: In accordance with the PRA (44 U.S.C. 3501 et seq.) and 5 CFR 1320.8(d)(1), we invite the public and other Federal agencies to comment on new, proposed, revised and continuing collections of information. This helps the BLM assess impacts of its information collection requirements and minimize the public's reporting burden. It also helps the public understand BLM information collection requirements and ensure requested data are provided in the desired format.

A Federal Register notice with a 60-day public comment period soliciting comments on this collection of information was published on August 15, 2022 (87 FR 50118). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again inviting the public and other Federal agencies to comment on the proposed ICR described below. The BLM is especially interested in public comment addressing the following:

- (1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- (2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used.
- (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and
- (4) How might the agency minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of response.

Comments submitted 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 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 BLM is required to manage commercial, competitive and organized group recreational uses of the public lands, and individual use of special areas. The BLM must assess, evaluate and authorize (permit) activities proposed to be conducted on public land. The estimated annual burden is estimated to increase by 308 hours (from 5,292 to 5,600). This increase in burden hours results from increasing the number of estimated annual responses from 1,323 to 1,400. The increase in the number of responses is a result of increase demand for recreation permits. This OMB Control Number is currently scheduled to expire on April 30, 2023. The BLM request that OMB renew this OMB Control Number for an additional three years.

Title of Collection: Permits for Recreation on Public Lands (43 CFR part 2930).

OMB Control Number: 1004–0119. Form Numbers: 2930–001—Special Recreation Application.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Applicants for recreational use of public lands managed by the BLM.

Total Estimated Number of Annual Respondents: 1,400.

Total Estimated Number of Annual Responses: 1,400.

Estimated Completion Time per Response: 4 hours.

Total Estimated Number of Annual Burden Hours: 5,600.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion. Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and, notwithstanding any other provision of law, 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 PRA of 1995 (44 U.S.C. 3501 *et seq.*).

Darrin King,

Information Collection Clearance Officer. [FR Doc. 2022–24700 Filed 11–10–22; 8:45 am] BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

National Park Service

Fish and Wildlife Service [PPWONRADE2, PMP00El05.YP0000]

Notice of Intent To Prepare North Cascades Ecosystem Grizzly Bear Restoration Plan/Environmental Impact Statement, Washington

AGENCIES: National Park Service and U.S. Fish and Wildlife Service, Interior. **ACTION:** Notice of intent.

SUMMARY: The National Park Service (NPS) and the U.S. Fish and Wildlife Service (FWS) are jointly preparing an environmental impact statement (EIS) for the North Cascades Ecosystem Grizzly Bear Restoration Plan to determine how to restore the grizzly bear to the North Cascades ecosystem (NCE), a portion of its historical range. As part of the planning and EIS process, the NPS and the FWS will evaluate various approaches for the restoration of a grizzly bear population to the NCE. Action is needed to restore grizzly bears to the NCE because they are functionally extirpated from the ecosystem, and restoration there will contribute to overall grizzly bear recovery.

DATES: All comments must be received or postmarked by December 14, 2022. **ADDRESSES:** *Comment submission:* To submit comments for consideration in development of the EIS, you may use any one of the following methods:

• Agency website: https://parkplanning.nps.gov/NCEGrizzly.

• U.S. mail: Office of the Superintendent, 810 State Route 20, Sedro-Woolley, WA 98284; or Washington Fish and Wildlife Office, 500 Desmond Dr. SE, Lacey, WA 98503.

Document availability: Information regarding the public scoping process for the EIS and virtual public meetings is available for public review online at https://parkplanning.nps.gov/NCEGrizzly; or, by appointment in the Office of the Superintendent, 810 State Route 20, Sedro-Woolley, WA 98284 (360–854–7200, telephone); and in the Washington Fish and Wildlife Office, 500 Desmond Dr. SE, Lacey, WA 98503 (360–753–9440, telephone).

FOR FURTHER INFORMATION CONTACT:

Denise Shultz, Public Information Officer, North Cascades National Park Service Complex, 810 State Route 20, Sedro-Woolley, WA 98284 (360–854– 7200; nce_grizzly@nps.gov), or Andrew LaValle, Public Affairs Specialist, Washington Fish and Wildlife Office, 500 Desmond Dr. SE, Lacey, WA 98503 (nce_grizzly@nps.gov).

SUPPLEMENTARY INFORMATION:

Purpose and Need

Pursuant to the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 et seq.; see 42 U.S.C. 4332(2)(C)), the NPS and the FWS are jointly preparing an NCE Grizzly Bear Restoration Plan and EIS. The purpose of the Grizzly Bear Restoration Plan is to determine how to restore the grizzly bear to the NCE, a portion of its historical range.

Action is needed at this time to:

• Restore grizzly bears to the NCE because they are functionally extirpated from the ecosystem.

• Contribute to the restoration of biodiversity of the ecosystem for the benefit and enjoyment of present and future generations of people.

• Enhance the probability of longterm survival of grizzly bears in the NCE and thereby contribute to overall grizzly bear recovery.

• Support the recovery of the grizzly bear to the point where it can be removed from the Federal List of Endangered and Threatened Wildlife.

Preliminary Proposed Action and Alternatives

As part of the planning and EIS process, the NPS and FWS will evaluate various approaches for the restoration of a grizzly bear population to the NCE. Preliminary alternatives to be considered in the EIS are described in greater detail below.

Actions Common to All Action Alternatives

All the action alternatives would seek to restore a self-sustaining population through the capture and release of grizzly bears into the NCE. Each of the action alternatives would involve several of the same elements, including a similar approach for the capture, release, and monitoring of grizzly bears; enhanced public education and outreach; guidelines for management actions to respond to human—grizzly bear conflicts; improved sanitation on public lands; additional releases of grizzly bears to replace individuals lost to mortality; access management; and habitat management.

No Action Alternative—Existing Management

Under the no action alternative, existing management practices would be followed, and no new management actions would be implemented. Existing management actions would continue to be focused on improved sanitation, poaching control, motorized access management, outreach and educational

programs to provide information about grizzly bears and grizzly bear recovery to the public, and research and monitoring to determine grizzly bear presence, distribution, habitat, and home ranges.

Proposed Action—Restoration as an Experimental Population Under the ESA

Under the proposed action, the NPS and the FWS would capture bears from source populations in either interior British Columbia or the Northern Continental Divide Ecosystem. Approximately 3 to 7 captured grizzly bears would be released into the NCE each year over roughly 5 to 10 years, with a goal of establishing an initial population of 25 grizzly bears. After the initial population of 25 grizzly bears has been reached, an adaptive management phase would allow additional bears to be released into the ecosystem over time to address mortality, population and demographic trends, genetic limitations, and distribution or to adjust the population's sex ratio to improve reproductive success. The proposed action is expected to result in a population of approximately 200 grizzly bears within 60 to 100 years.

The proposed action would also include a proposal to designate the reintroduced grizzly bears in the NCE as an experimental population under section 10(j) of the U.S. Endangered Species Act (ESA; 16 U.S.C. 1531 et seq.). An experimental population is a group of reintroduced plants or animals that is geographically isolated from other populations of the species. Experimental populations must contribute to a species' recovery and may include special protective regulations under the ESA. Designation of grizzly bears released into the NCE as an experimental population would allow the FWS to specify protective regulations to provide greater management flexibility (e.g., relocation or removal) in the event of humangrizzly bear conflict situations.

Other Potential Alternatives

Additional alternatives may be analyzed in the EIS. Potential additional alternatives include restoring the NCE grizzly population without an experimental population designation, as well as varying the number and frequency of grizzly bear releases into the NCE to achieve the restoration goal in a shorter or longer time period.

Summary of Expected Impacts

The proposed action is expected to result in restoration of a grizzly bear population in the NCE. Expected impacts from implementation of grizzly bear restoration actions include potential environmental impacts on wildlife and fish (including grizzly bears), wilderness, visitor use and recreational experience, public and employee safety, socioeconomics, and ethnographic resources.

Anticipated Permits and Authorizations

The NPS and the FWS will comply with the ESA for potential impacts to threatened and endangered species. If a decision is made to pursue rulemaking, the FWS will lead the experimental population rulemaking process. The NPS and the FWS will use and coordinate the NEPA public scoping process to help fulfill the public involvement requirements under the National Historic Preservation Act (54 U.S.C. 306108) as provided in title 36 of the Code of Federal Regulations (CFR) at § 800.2(d)(3). The information about historic and cultural resources within the area potentially affected by the alternatives will assist the NPS and the FWS in identifying and evaluating impacts to such resources, and consulting with affected Indian Tribes and the State Historic Preservation Officer(s).

Schedule for the Decision-Making Process

- Agencies have 2 years from the date of the issuance of the notice of intent to the date a record of decision is signed to complete an EIS (40 CFR 1501.10).
- The NPS and the FWS expect to make the draft EIS available to the public in the summer of 2023.
- After public review and comment, the NPS and the FWS expect to make the final EIS available to the public in the spring of 2024.
- The NPS and the FWS would issue a record of decision after the final EIS in accordance with the applicable timeframes under 40 CFR 1506.11.

Public Scoping Process

This notice of intent initiates the scoping process, which guides the development of the EIS. The NPS and the FWS will host virtual public scoping meetings. During the virtual public scoping meetings, the NPS and the FWS will present information pertinent to the EIS and allow the public to ask questions regarding the scope of issues and alternatives that should be considered when preparing the EIS. While the NPS and the FWS will not solicit oral comments at these virtual public meetings, written comments may be submitted at any time during the scoping process. See ADDRESSES, above, and Submitting Comments, below, for more information. Details regarding the

exact dates and times of these virtual public scoping meetings will be announced on the project website (https://parkplanning.nps.gov/NCEGrizzly) and through local and regional media. The virtual public scoping meetings will also be announced through email notification to individuals and organizations, press release, and social media.

The NPS and FWS will also seek to engage directly with Tribes. Consistent with Executive Order 13175, the NPS and FWS welcome Tribal input and are available to engage in meaningful government-to-government consultation with Tribes at their request.

The NPS and the FWS previously proposed to restore grizzly bears to the NCE and produced a draft EIS for public review and comment in 2017 (82 FR 4416, January 13, 2017). Public comments that were provided during that prior EIS process will also inform this new EIS and the development of alternatives.

Reasonable Accommodations

Persons needing reasonable accommodations to attend and participate in the virtual public scoping meetings should contact Denise Shultz (NPS) or Andrew LaValle (FWS) using one of the methods listed in FOR FURTHER INFORMATION CONTACT as soon as possible. To allow sufficient time to process requests, please make contact no later than 1 week before the desired virtual public meeting.

Request for Identification of Potential Alternatives, Information, and Analyses Relevant to the Proposed Action

The NPS and the FWS request comments concerning the scope of the analysis, identification of potential alternatives, and information and analyses relevant to the planning process. The NPS and the FWS will consider these comments in developing the draft EIS. Specifically, the NPS and the FWS are seeking information on:

- Potential effects that the alternatives could have on other aspects of the human environment, including ecological, aesthetic, historic, cultural, economic, social, environmental justice, or health effects;
- Other possible reasonable alternatives that the NPS and the FWS should consider, including additional or alternative avoidance, minimization, and mitigation measures;
- Approaches for managing reintroduced grizzly bears, particularly in regard to potential conflicts with human activities; and

• Other information relevant to grizzly bear restoration and its impacts on the human environment.

Submitting Comments

If you wish to comment, you may submit comments by one of the methods listed above in ADDRESSES. Comments will not be accepted by fax, email, or by any method other than those specified above. Bulk comments in any format (hard copy or electronic) submitted on behalf of others will not be accepted. Comments must be provided by the close of the comment period and should clearly articulate the submitter's concerns and contentions.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. Comments submitted anonymously will be accepted and considered.

Decision Makers

The decision makers are the NPS Regional Director for Interior Regions 8, 9, 10, and 12 and the FWS Regional Director for the Pacific Region.

Frank Lands,

Regional Director, Interior Regions 8, 9, 10, & 12, National Park Service.

Nanette Seto,

Acting Regional Director, Pacific Region, U.S. Fish and Wildlife Service.

[FR Doc. 2022–24717 Filed 11–10–22; 8:45 am] BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337-TA-1340]

Certain Electronic Devices, Semiconductor Devices, and Components Thereof Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on October 6, 2022, under section 337 of the Tariff Act of 1930, as amended, on behalf of Bell Semiconductor, LLC of

Bethlehem, Pennsylvania. Supplements to the complaint were filed on October 21 and 28, 2022. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain electronic devices, semiconductor devices, and components thereof by reason of infringement of certain claims of U.S. Patent No. 7,231,626 ("the '626 Patent") and U.S. Patent No. 7,260,803 ("the '803 Patent"). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at https://edis.usitc.gov. For help accessing EDIS, please email EDIS3Help@usitc.gov. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205-2000. General information concerning the Commission may also be obtained by accessing its internet server at https://www.usitc.gov.

FOR FURTHER INFORMATION CONTACT:

Pathenia M. Proctor, The Office of Unfair Import Investigations, (202) 205– 2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2022).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on November 7, 2022, ordered that—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims

1–6 and 9–11 of the '803 patent and claims 1–4 of the '626 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is "semiconductor devices, and specifically undiced wafers, diced wafers, packaged chips and chipsets both attached and unattached to printed circuit boards; and end products incorporating such articles, specifically cellular telephones and tablet computers, personal computers, graphics cards, memory modules, and radios";

(3) Pursuant to Commission Rule 210.50(b)(l), 19 CFR 210.50(b)(1), the presiding administrative law judge shall take evidence or other information and hear arguments from the parties or other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. l337(d)(l), (f)(1), (g)(1);

(4) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is:

Bell Semiconductor, LLC, One West Broad Street, Suite 901, Bethlehem, PA 18018.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served: NXP Semiconductors, N.V., 60 High Tech Campus, Eindhoven, Netherlands, 5656

NXP B.V., 60 High Tech Campus, Eindhoven, Netherlands, 5656 NXP USA, Inc., 6501 William Cannon Drive West, Austin, TX 78735

SMC Networks, Inc. d/b/a/IgniteNet, 20 Mason, Irvine, CA 92618 Micron Technology, Inc. 8000 South

Micron Technology, Inc., 8000 South Federal Way, PO Box 6, Boise, ID 83707

NVIDIA Corporation, 2788 San Tomas Expressway, Santa Clara, CA 95051 Advanced Micro Devices, Inc., 2485 Augustine Drive, Santa Clara, CA 05054

Acer, Inc., 1F, 88, Sec. 1, Xintai 5th Rd. Xizhi, New Taipei City 221, Taiwan Acer America Corporation, 333 West San Carlos Street Suite 1500, San Jose, CA 95110 Infineon Technologies AG, Biberger Strasse 93, 82008 Neubiberg, Germany

Infineon Technologies America Corp., 640 N McCarthy Blvd., Milpitas, CA 95035

Motorola Mobility LLC, 222 W Merchandise Mart Plaza, Suite 1800, Chicago, IL 60654

Western Digital Technologies, Inc., 5601 Great Oaks Parkway, San Jose, CA 95119

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW, Suite 401, Washington, DC 20436; and

(5) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainant of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission. Issued: November 8, 2022.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2022–24721 Filed 11–10–22; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Marine Air*Conditioning Systems, Components Thereof, and Products Containing the Same, DN 3654; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT:

Katherine M. Hiner, Acting Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205-2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at https:// edis.usitc.gov. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at https://www.usitc.gov. The public record for this investigation may be viewed on the Commission's **Electronic Document Information** System (EDIS) at https://edis.usitc.gov. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Dometic Corporation and Dometic Sweden AB on November 7, 2022. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of regarding certain marine air conditioning systems, components thereof, and products containing the same. The complainant names as respondents: Shanghai Hopewell Industrial Co. Ltd. of China; Shanghai Hehe Industrial Co. Ltd. of China; CitiMarine, L.L.C. of Doral, FL; and Mabru Power Systems, Inc. of Dania

Beach, FL. The complainant requests that the Commission issue a limited exclusion order and cease and desist orders, and impose a bond upon respondent's alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders:

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the Federal Register. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the Federal Register. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice

are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number ("Docket No. 3654") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, Electronic Filing Procedures.) 1 Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, https:// edis.usitc.gov.) No in-person paperbased filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the

Secretary at EDIS3Help@usitc.gov. Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,² solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.3

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission. Issued: November 7, 2022.

Katherine M. Hiner,

 $Acting \, Secretary \, to \, the \, Commission. \\ [FR \, Doc. \, 2022-24656 \, Filed \, 11-10-22; \, 8:45 \, am]$

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On November 4, 2022, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Southern District of Ohio in the lawsuit entitled *United States* v. *Utica Resource Operating, LLC,* Case No. 22–cv–3906 (S.D. Ohio).

The Complaint seeks civil penalties and injunctive relief relating to a number of oil and natural gas production well pads that Utica Resource Operating, LLC ("URO") operates in Ohio. The claims in the Complaint arise from URO's alleged failure to comply with the CAA rules for preventing uncontrolled emissions of volatile organic compounds from dozens of large tanks that store crude oil and oily wastewater at the facilities. The Complaint alleges violations relating to noncompliance with storage vessel cover and closed vent system requirements, combustor operation requirements, and inspection and recordkeeping requirements. Under the Consent Decree, URO would be required to take a number of measures to come into compliance with the law. In particular, the proposed Consent Decree requires URO to pay a \$1 million civil penalty, complete a suite of injunctive relief at fifteen well pads to come into compliance with the NSPS and the facilities' operating permits, and implement mitigation measures at many of the well pads owned by URO. The Consent Decree requires a multi-step compliance program to review the current design of each tank and vapor control system and then make necessary design improvements to ensure that vapors will not be released to the atmosphere during operations.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Utica Resource Operating, LLC, D.J. Ref. No.* 90–5–2–1–12514. All comments must be submitted no later than 30 days after the publication date of this notice.

¹ Handbook for Electronic Filing Procedures: https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.

 $^{^2\,\}mathrm{All}$ contract personnel will sign appropriate nondisclosure agreements.

³ Electronic Document Information System (EDIS): https://edis.usitc.gov.

Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By email	pubcomment-ees.enrd@ usdoj.gov.
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: https://www.justice.gov/enrd/consent-decrees. We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for \$10.75 (25 cents per page reproduction cost) payable to the United States Treasury.

Patricia McKenna,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2022-24680 Filed 11-10-22; 8:45 am]

BILLING CODE 4410-15-P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petition for Modification of Application of Existing Mandatory Safety Standards

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: This notice is a summary of a petition for modification submitted to the Mine Safety and Health Administration (MSHA) by the party listed below.

DATES: All comments on the petition must be received by MSHA's Office of Standards, Regulations, and Variances on or before December 14, 2022.

ADDRESSES: You may submit comments identified by Docket No. MSHA-2022-0059 by any of the following methods:

- 1. Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments for MSHA-2022-0059.
 - 2. Fax: 202-693-9441.
 - 3. Email: petitioncomments@dol.gov.
- 4. Regular Mail or Hand Delivery: MSHA, Office of Standards,

Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202-5452. Attention: S. Aromie Noe, Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect copies of the petition and comments during normal business hours at the address listed above. Before visiting MSHA in person, call 202-693-9455 to make an appointment, in keeping with the Department of Labor's COVID-19 policy. Special health precautions may be required.

FOR FURTHER INFORMATION CONTACT: S. Aromie Noe, Office of Standards, Regulations, and Variances at 202–693–9440 (voice), Petitionsformodification@dol.gov (email), or 202–693–9441 (fax). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations (CFR) part 44 govern the application, processing, and disposition of petitions for modification.

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

- 1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or
- 2. The application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, sections 44.10 and 44.11 of 30 CFR establish the requirements for filing petitions for modification.

II. Petition for Modification

Docket Number: M-2022-024-C. Petitioner: Panther Creek Mining, 250 West Main Street, Suite 2000, Lexington, Kentucky, 40507.

Mine: Maple Eagle No. 1 Mine, MSHA ID No. 46–04236, located in Fayette County, West Virginia.

Regulation Affected: 30 CFR 75.507–1(a), Electric equipment other than power-connection points; outby the last open crosscut; return air; permissibility requirements.

Modification Request: The petitioner requests a modification of 30 CFR 75.507–1(a) to permit the use of battery-

powered nonpermissible surveying equipment, including, but not limited to, portable battery operated mine transits, total station surveying equipment, distance meters, and data loggers in return airways.

The petitioner states that:

(a) To comply with requirements of 30 CFR 75.372 use of the most practical and accurate surveying equipment is necessary.

(b) Mechanical surveying equipment has been obsolete for several years. Such equipment of acceptable quality is not commercially available, and it is difficult, if not impossible, to have such equipment serviced or repaired.

(c) Electronic surveying equipment is, at a minimum, eight to ten times more accurate than mechanical equipment.

(d) Underground mining by its nature, size and complexity of mine plans requires that accurate and precise measurements be completed in a prompt and efficient manner.

The petitioner proposes the following

alternative method:

(a) Using the following total station and theodolite and similar low voltage battery-operated total stations and theodolites with an ingress protection (IP) rating of 66 or greater in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces subject to the conditions of the Decision and Order:

(1) Topcom GPT-3002LW.

(b) The equipment allowed under the Decision and Order is low voltage or battery-powered non-permissible total stations and theodolites with an IP rating of 66 or greater.

(c) The operator shall maintain a logbook for electronic surveying equipment with the equipment, in the location where mine record books are kept, or in the location where the surveying record books are kept. The logbook will contain the date of manufacture and/or purchase of each piece of electronic surveying equipment. The logbook shall be made available to MSHA upon request.

- (d) All non-permissible electronic surveying equipment to be used in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces shall be examined by the person to operate the equipment prior to taking the equipment underground to ensure the equipment is maintained in a safe operating condition. These examinations shall include:
- (1) Checking the instrument for any physical damage and the integrity of the case:
- (2) Removing the battery and inspecting for corrosion;

(3) Inspecting the contact points to ensure a secure connection to the

(4) Řeinserting the battery and powering up and shutting down to ensure proper connections; and

(5) Checking the battery compartment cover or battery attachment to ensure that it is securely fastened.

The results of this examination shall be recorded in the logbook.

(e) The equipment shall be examined at least weekly by a qualified person as defined in 30 CFR 75.153; the examination results shall be recorded weekly in the equipment's logbook. Examination entries in the logbook may

be expunged after 1 year.

(f) The operator shall ensure that all non-permissible electronic surveying equipment is serviced according to the manufacturer's recommendations. Dates of service shall be recorded in the equipment's logbook and shall include a description of the work performed.

(g) The non-permissible surveying equipment to be used in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces shall not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of the Decision and Order.

(h) Non-permissible surveying equipment shall not be used if methane is detected in concentrations at or above 1.0 percent methane. When 1.0 percent or more of methane is detected while the non-permissible surveying equipment is being used, the equipment shall be de-energized immediately and the non-permissible electronic equipment withdrawn outby the last open crosscut, out of the return, or more than 150 feet from pillar workings or longwall faces. All requirements of 30 CFR 75.323 shall be complied with prior to entering in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces.

(i) As an additional safety check, prior to setting up and energizing nonpermissible electronic surveying equipment in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces, the surveyor(s) shall conduct a visual examination of the immediate area for evidence that the area appears to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated float coal dust is observed, the equipment shall not be energized until sufficient rock dust has been applied and/or the accumulations of float coal dust have been removed. If nonpermissible

electronic surveying equipment is to be used in an area that has not been rockdusted within 40 feet of a working face where a continuous mining machine is used to extract coal, the area shall be rock-dusted prior to energizing the electronic surveying equipment.

(j) All hand-held methane detectors shall be MSHA-approved and maintained in permissible and proper operating condition as defined by 30 CFR 75.320. All methane detectors shall provide visual and audible warnings when methane is detected at or above 1.0 percent.

(k) Prior to energizing any of the nonpermissible surveying equipment in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces, methane tests shall be made in accordance with 30 CFR 75.323(a).

(l) All areas to be surveyed must be pre-shifted according to 30 CFR 75.360 prior to surveying. If the area was not pre-shifted, a supplemental examination according to 30 CFR 75.361 shall be performed before any non-certified person enters the area. If the area has been examined according to 30 CFR 75.360 or 30 CFR 75.361, additional

examination is not required.

(m) A qualified person as defined in 30 CFR 75.151 shall continuously monitor for methane immediately before and during the use of non-permissible surveying equipment in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces. A second person in the surveying crew, if there are two people in the crew, shall also continuously monitor for methane. That person shall be a qualified person as defined in 30 CFR 75.151 or be in the process of being trained to be a qualified person but have yet to "make such tests for a period of 6 months" as required by 30 CFR 75.150. Upon completion of the 6month training period, the second person on the surveying crew shall become qualified in order to continue on the surveying crew. If the surveying crew consists of only one person, they shall monitor for methane with two separate devices.

(n) Batteries contained in the surveying equipment shall be changed out or charged in intake air outby the last open crosscut, out of the return, and more than 150 feet away from pillar workings or the longwall face. Replacement batteries for the electronic surveying equipment shall be carried only in the electronic equipment carrying case spare battery compartment. Before each surveying shift, all batteries for the electronic surveying equipment shall be charged

sufficiently that they are not expected to be replaced on that shift.

- (o) When using non-permissible electronic surveying equipment in or inby the last open crosscut, in the return, or within 150 feet of the pillar workings or longwall faces, the surveyor shall confirm by measurement or by inquiry of the person in charge of the section that the air quantity on the section, on that shift, in the last open crosscut is at least the minimum quantity required by the mine's ventilation plan.
- (p) Personnel engaged in the use of surveying equipment shall be properly trained to recognize the hazards and limitations associated with the use of surveying equipment in areas where methane could be present.
- (q) All members of the surveying crew shall receive specific training on the terms and conditions of the Decision and Order before using non-permissible electronic equipment in or inby the last open crosscut, in the return, or within 150 feet of the pillar workings or longwall face. A record of the training shall be kept with the other training records.
- (r) Within 60 days after any granted Decision and Order becomes final, the operator shall submit proposed revisions for its approved 30 CFR part 48 training plans to the Coal Mine Safety and Health District Manager. These proposed revisions shall specify initial and refresher training regarding the terms and conditions of the Decision and Order. When training is conducted on the terms and conditions of the Decision and Order, a MSHA Certificate of Training (Form 5000-23) shall be completed and shall include comments indicating it was surveyor training.
- (s) The operator shall replace or retire from service any electronic surveying instrument acquired prior to December 31, 2004, within 1 year of the Decision and Order becoming final. Within 3 years of the date the Decision and Order becomes final, the operator shall replace or retire from service any theodolite acquired more than 5 years prior to the date the granted Decision and Order became final and any total station or other electronic surveying equipment identified in the Decision and Order acquired more than 10 years prior to the date the Decision and Order became final. After 5 years, the operator shall maintain a cycle of purchasing new electronic surveying equipment so that theodolites shall be no older than 5 years from date of manufacture and total stations and other electronic surveying equipment shall be no older than 10 years from date of manufacture.

- (t) The operator is responsible for ensuring that all surveying contractors hired by the operator use electronic equipment in accordance with the requirements of item (s). The conditions of use specified in the Decision and Order shall apply to all non-permissible electronic surveying equipment used in or inby the last open crosscut, in a return, or within 150 feet of pillar workings or longwall faces regardless of whether the equipment is used by the operator or by an independent contractor.
- (u) Non-permissible surveying equipment may be used when production is occurring, subject to these conditions:
- (1) On a mechanized mining unit (MMU) where production is occurring, non-permissible electronic surveying equipment shall not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as "baloney skins") or curtains.

(2) Production may continue while non-permissible electronic surveying equipment is used if the surveying equipment is used in a separate split of air from where production is occurring.

(3) Non-permissible surveying equipment shall not be used in a split of air ventilating a MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's approved ventilation plan.

(4) If while surveying a surveyor must disrupt ventilation, the surveyor shall cease surveying and communicate to the section foreman that ventilation must be disrupted. Production shall stop while ventilation is disrupted. Ventilation controls shall be reestablished immediately after the disruption is no longer necessary. Production shall only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans and other applicable laws, standards, or

regulations.
(5) Any disruption in ventilation shall be recorded in the logbook required by the Decision and Order. The logbook shall include a description of the nature of the disruption, the location of the

disruption, the date and time of the

disruption, the date and time the

surveyor communicated the disruption to the section foreman, the date and time production ceased, the date and time ventilation was reestablished, and the date and time production resumed.

(6) All surveyors, section foremen, section crew members, and other

personnel who will be involved with or affected by surveying operations shall receive training in accordance with 30 CFR 48.7 on the requirements of the Decision and Order within 60 days of the date the Decision and Order becomes final. Such training shall be completed before any non-permissible surveying equipment can be used while production is occurring. The operator shall keep a record of such training and provide it to MSHA upon request.

(7) The operator shall provide annual retraining to all personnel who will be involved with or affected by surveying operations in accordance with 30 CFR 48.8. The operator shall train new miners on the requirements of the Decision and Order in accordance with 30 CFR 48.5 and shall train experienced miners, as defined in 30 CFR 48.6, on the requirements of the Decision and Order in accordance with 30 CFR 48.6. The operator shall keep a record of such training and provide it to MSHA upon request

The petitioner asserts that the alternative method proposed will at all times guarantee no less than the same measure of protection afforded the miners under the mandatory standard.

Song-ae Aromie Noe,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2022–24672 Filed 11–10–22; 8:45 am]

BILLING CODE 4510-43-P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petition for Modification of Application of Existing Mandatory Safety Standards

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: This notice is a summary of a petition for modification submitted to the Mine Safety and Health Administration (MSHA) by the party listed below.

DATES: All comments on the petition must be received by MSHA's Office of Standards, Regulations, and Variances on or before December 14, 2022.

ADDRESSES: You may submit comments identified by Docket No. MSHA-2022-0060 by any of the following methods:

- 1. Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments for MSHA-2022-0060.
 - 2. Fax: 202-693-9441.
 - 3. Email: petitioncomments@dol.gov.

4. Regular Mail or Hand Delivery: MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452.

Attention: S. Aromie Noe, Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect copies of the petition and comments during normal business hours at the address listed above. Before visiting MSHA in person, call 202–693–9455 to make an appointment, in keeping with the Department of Labor's COVID–19 policy. Special health precautions may be required.

FOR FURTHER INFORMATION CONTACT: S. Aromie Noe, Office of Standards, Regulations, and Variances at 202–693–9440 (voice), Petitionsformodification®

9440 (voice), Petitionsformodification@dol.gov (email), or 202–693–9441 (fax). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations (CFR) part 44 govern the application, processing, and disposition of petitions for modification.

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

- 1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or
- 2. The application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, sections 44.10 and 44.11 of 30 CFR establish the requirements for filing petitions for modification.

II. Petition for Modification

Docket Number: M-2022-025-C. Petitioner: Panther Creek Mining, 250 West Main Street, Suite 2000, Lexington, Kentucky, 40507.

Mine: Maple Eagle No. 1 Mine, MSHA ID No. 46–04236, located in Fayette County, West Virginia.

Regulation Affected: 30 CFR 75.500(d), Permissible electric equipment.

Modification Request: The petitioner requests a modification of 30 CFR

75.500(d) to permit the use of battery-powered nonpermissible surveying equipment, including, but not limited to, portable battery operated mine transits, total station surveying equipment, distance meters, and data loggers in or inby the last open crosscut.

The petitioner states that:

(a) To comply with requirements of 30 CFR 75.372 and 30 CFR 75.1200 use of the most practical and accurate surveying equipment is necessary.

(b) Mechanical surveying equipment has been obsolete for several years. Such equipment of acceptable quality is not commercially available, and it is difficult, if not impossible, to have such equipment serviced or repaired.

(c) Electronic surveying equipment is, at a minimum, eight to ten times more accurate than mechanical equipment.

(d) The mine uses the continuous mining machine method of mining.

(e) Accurate surveying is critical to

the safety of the miners.

(f) Underground mining by its nature, size and complexity of mine plans requires that accurate and precise measurements be completed in a prompt and efficient manner.

The petitioner proposes the following alternative method:

(a) Using the following total station and theodolite and similar low voltage battery-operated total stations and theodolites with an ingress protection (IP) rating of 66 or greater in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces subject to the conditions of the Decision and Order:

(1) Topcom GPT-3002LW.

(b) The equipment allowed under the Decision and Order is low voltage or battery-powered non-permissible total stations and theodolites with an IP rating of 66 or greater.

(c) The operator shall maintain a logbook for electronic surveying equipment with the equipment, in the location where mine record books are kept, or in the location where the surveying record books are kept. The logbook will contain the date of manufacture and/or purchase of each piece of electronic surveying equipment. The logbook shall be made available to MSHA upon request.

(d) All non-permissible electronic surveying equipment to be used in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces shall be examined by the person to operate the equipment prior to taking the equipment underground to ensure the equipment is maintained in a safe operating condition. These examinations shall include:

(1) Checking the instrument for any physical damage and the integrity of the case:

(2) Removing the battery and inspecting for corrosion;

(3) Inspecting the contact points to ensure a secure connection to the battery;

(4) Keinserting the battery and powering up and shutting down to ensure proper connections; and

(5) Checking the battery compartment cover or battery attachment to ensure that it is securely fastened.

The results of this examination shall

be recorded in the logbook.

(e) The equipment shall be examined at least weekly by a qualified person as defined in 30 CFR 75.153; the examination results shall be recorded weekly in the equipment's logbook. Examination entries in the logbook may be expunged after 1 year.

(f) The operator shall ensure that all non-permissible electronic surveying equipment is serviced according to the manufacturer's recommendations. Dates of service shall be recorded in the equipment's logbook and shall include a description of the work performed.

(g) The non-permissible surveying equipment to be used in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces shall not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of the Decision and Order.

(h) Non-permissible surveying equipment shall not be used if methane is detected in concentrations at or above 1.0 percent methane. When 1.0 percent or more of methane is detected while the non-permissible surveying equipment is being used, the equipment shall be de-energized immediately and the non-permissible electronic equipment withdrawn outby the last open crosscut, out of the return, or more than 150 feet from pillar workings or longwall faces. All requirements of 30 CFR 75.323 shall be complied with prior to entering in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces.

(i) As an additional safety check, prior to setting up and energizing nonpermissible electronic surveying equipment in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces, the surveyor(s) shall conduct a visual examination of the immediate area for evidence that the area appears to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated float

coal dust is observed, the equipment shall not be energized until sufficient rock dust has been applied and/or the accumulations of float coal dust have been removed. If nonpermissible electronic surveying equipment is to be used in an area that has not been rockdusted area within 40 feet of a working face where a continuous mining machine is used to extract coal, the area shall be rock-dusted prior to energizing the electronic surveying equipment.

(j) All hand-held methane detectors shall be MSHA-approved and maintained in permissible and proper operating condition as defined by 30 CFR 75.320. All methane detectors shall provide visual and audible warnings when methane is detected at or above

1.0 percent.

(k) Prior to energizing any of the nonpermissible surveying equipment in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces, methane tests shall be made in accordance with 30 CFR 75.323(a).

(l) All areas to be surveyed must be pre-shifted according to 30 CFR 75.360 prior to surveying. If the area was not pre-shifted, a supplemental examination according to 30 CFR 75.361 shall be performed before any non-certified person enters the area. If the area has been examined according to 30 CFR 75.360 or 30 CFR 75.361, additional

examination is not required.

(m) A qualified person as defined in 30 CFR 75.151 shall continuously monitor for methane immediately before and during the use of non-permissible surveying equipment in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces. A second person in the surveying crew, if there are two people in the crew, shall also continuously monitor for methane. That person shall be a qualified person as defined in 30 CFR 75.151 or be in the process of being trained to be a qualified person but have yet to "make such tests for a period of 6 months" as required by 30 CFR 75.150. Upon completion of the 6month training period, the second person on the surveying crew shall become qualified in order to continue on the surveying crew. If the surveying crew consists of only one person, they shall monitor for methane with two separate devices.

(n) Batteries contained in the surveying equipment shall be changed out or charged in intake air outby the last open crosscut, out of the return, and more than 150 feet away from pillar workings or the longwall face.

Replacement batteries for the electronic surveying equipment shall be carried

only in the electronic equipment carrying case spare battery compartment. Before each surveying shift, all batteries for the electronic surveying equipment shall be charged sufficiently that they are not expected to

be replaced on that shift.

(o) When using non-permissible electronic surveying equipment in or inby the last open crosscut, in the return, or within 150 feet of the pillar workings or longwall faces, the surveyor shall confirm by measurement or by inquiry of the person in charge of the section that the air quantity on the section, on that shift, in the last open crosscut is at least the minimum quantity required by the mine's ventilation plan.

(p) Personnel engaged in the use of surveying equipment shall be properly trained to recognize the hazards and limitations associated with the use of surveying equipment in areas where

methane could be present.

(q) All members of the surveying crew shall receive specific training on the terms and conditions of the Decision and Order before using non-permissible electronic equipment in or inby the last open crosscut, in the return, or within 150 feet of the pillar workings or longwall face. A record of the training shall be kept with the other training records.

(r) Within 60 days after any granted Decision and Order becomes final, the operator shall submit proposed revisions for its approved 30 CFR part 48 training plans to the Coal Mine Safety and Health District Manager. These proposed revisions shall specify initial and refresher training regarding the terms and conditions of the Decision and Order. When training is conducted on the terms and conditions of the Decision and Order, a MSHA Certificate of Training (Form 5000–23) shall be completed and shall include comments indicating it was surveyor training.

(s) The operator shall replace or retire from service any electronic surveying instrument acquired prior to December 31, 2004, within 1 year of the Decision and Order becoming final. Within 3 years of the date the Decision and Order becomes final, the operator shall replace or retire from service any theodolite acquired more than 5 years prior to the date the granted Decision and Order became final and any total station or other electronic surveying equipment identified in the Decision and Order acquired more than 10 years prior to the date the Decision and Order became final. After 5 years, the operator shall maintain a cycle of purchasing new electronic surveying equipment so that theodolites shall be no older than 5

years from date of manufacture and total stations and other electronic surveying equipment shall be no older than 10 years from date of manufacture.

(t) The operator is responsible for ensuring that all surveying contractors hired by the operator use electronic equipment in accordance with the requirements of item(s). The conditions of use specified in the Decision and Order shall apply to all non-permissible electronic surveying equipment used in or inby the last open crosscut, in a return, or within 150 feet of pillar workings or longwall faces regardless of whether the equipment is used by the operator or by an independent contractor.

- (u) Non-permissible surveying equipment may be used when production is occurring, subject to these conditions:
- (1) On a mechanized mining unit (MMU) where production is occurring, non-permissible electronic surveying equipment shall not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as "baloney skins") or curtains.
- (2) Production may continue while non-permissible electronic surveying equipment is used if the surveying equipment is used in a separate split of air from where production is occurring.
- (3) Non-permissible surveying equipment shall not be used in a split of air ventilating a MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's approved ventilation plan.

(4) If while surveying a surveyor must disrupt ventilation, the surveyor shall cease surveying and communicate to the section foreman that ventilation must be disrupted. Production shall stop while ventilation is disrupted. Ventilation controls shall be reestablished immediately after the disruption is no longer necessary. Production shall only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans and other applicable laws, standards, or regulations.

(5) Any disruption in ventilation shall be recorded in the logbook required by the Decision and Order. The logbook shall include a description of the nature of the disruption, the location of the disruption, the date and time of the disruption, the date and time the surveyor communicated the disruption to the section foreman, the date and time production ceased, the date and

time ventilation was reestablished, and the date and time production resumed.

(6) All surveyors, section foremen, section crew members, and other personnel who will be involved with or affected by surveying operations shall receive training in accordance with 30 CFR 48.7 on the requirements of the Decision and Order within 60 days of the date the Decision and Order becomes final. Such training shall be completed before any non-permissible surveying equipment can be used while production is occurring. The operator shall keep a record of such training and provide it to MSHA upon request.

(7) The operator shall provide annual retraining to all personnel who will be involved with or affected by surveying operations in accordance with 30 CFR 48.8. The operator shall train new miners on the requirements of the Decision and Order in accordance with 30 CFR 48.5 and shall train experienced miners, as defined in 30 CFR 48.6, on the requirements of the Decision and Order in accordance with 30 CFR 48.6. The operator shall keep a record of such training and provide it to MSHA upon request.

The petitioner asserts that the alternative method proposed will at all times guarantee no less than the same measure of protection afforded the miners under the mandatory standard.

Song-ae Aromie Noe,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2022–24673 Filed 11–10–22; 8:45 am] BILLING CODE 4520–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petition for Modification of Application of Existing Mandatory Safety Standards

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: This notice is a summary of a petition for modification submitted to the Mine Safety and Health Administration (MSHA) by the party listed below.

DATES: All comments on the petition must be received by MSHA's Office of Standards, Regulations, and Variances on or before December 14, 2022.

ADDRESSES: You may submit comments identified by Docket No. MSHA-2022-0058 by any of the following methods:

1. Federal eRulemaking Portal: https://www.regulations.gov. Follow the

instructions for submitting comments for MSHA–2022–0058.

- 2. Fax: 202-693-9441.
- 3. Email: petitioncomments@dol.gov.4. Regular Mail or Hand Delivery:
- MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington,

Virginia 22202-5452.

Attention: S. Aromie Noe, Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect copies of the petition and comments during normal business hours at the address listed above. Before visiting MSHA in person, call 202–693–9455 to make an appointment, in keeping with the Department of Labor's COVID–19 policy. Special health precautions may be required.

FOR FURTHER INFORMATION CONTACT: S.

Aromie Noe, Office of Standards, Regulations, and Variances at 202–693– 9440 (voice), *Petitionsformodification@dol.gov* (email), or 202–693–9441 (fax). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations (CFR) part 44 govern the application, processing, and disposition of petitions for modification.

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

- 1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or
- 2. The application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, sections 44.10 and 44.11 of 30 CFR establish the requirements for filing petitions for modification.

II. Petition for Modification

Docket Number: M-2022-023-C. Petitioner: Panther Creek Mining, 250 West Main Street, Suite 2000, Lexington, Kentucky 40507.

Mine: Maple Eagle No. 1 Mine, MSHA ID No. 46–04236, located in Fayette County, West Virginia.

Regulation Affected: 30 CFR 75.1002(a), Installation of electric

equipment and conductors; permissibility.

Modification Request: The petitioner requests a modification of 30 CFR 75.1002(a) to permit the use of battery-powered nonpermissible surveying equipment, including, but not limited to, portable battery operated mine transits, total station surveying equipment, distance meters, and data loggers within 150 feet of pillar workings or longwall faces.

The petitioner states that:

(a) To comply with requirements of 30 CFR 75.372, 75.1002(a), and 75.1200, use of the most practical and accurate surveying equipment is necessary.

(b) To ensure the safety of the miners in active mines and to protect miners in future mines which may mine near these same active mines, it is necessary to determine the exact location and extents of the mine workings.

(c) Mechanical surveying equipment has been obsolete for several years. Such equipment of acceptable quality is not commercially available, and it is difficult, if not impossible, to have such equipment serviced or repaired.

(d) Electronic surveying equipment is, at a minimum, eight to ten times more accurate than mechanical equipment.

(e) Underground mining by its nature, size and complexity of mine plans requires that accurate and precise measurements be completed in a prompt and efficient manner.

The petitioner proposes the following

alternative method:

(a) Using the following total station and theodolite and similar low voltage battery-operated total stations and theodolites with an ingress protection (IP) rating of 66 or greater in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces subject to the conditions of the Decision and Order:

(1) Topcom GPT–3002LW.

(b) The equipment allowed under the Decision and Order is low voltage or battery powered non-permissible total stations and theodolites with an IP rating of 66 or greater.

(c) The operator shall maintain a logbook for electronic surveying equipment with the equipment, in the location where mine record books are kept, or in the location where the surveying record books are kept. The logbook will contain the date of manufacture and/or purchase of each piece of electronic surveying equipment. The logbook shall be made available to MSHA upon request.

(d) All non-permissible electronic surveying equipment to be used in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces shall be examined by the person to operate the equipment prior to taking the equipment underground to ensure the equipment is maintained in a safe operating condition. These examinations shall include:

(1) Checking the instrument for any physical damage and the integrity of the

case;

(2) Removing the battery and inspecting for corrosion;

(3) Inspecting the contact points to ensure a secure connection to the battery;

(4) Reinserting the battery and powering up and shutting down to ensure proper connections; and

(5) Checking the battery compartment cover or battery attachment to ensure that it is securely fastened.

The results of this examination shall

be recorded in the logbook.

(e) The equipment shall be examined at least weekly by a qualified person as defined in 30 CFR 75.153; the examination results shall be recorded weekly in the equipment's logbook. Examination entries in the logbook may be expunged after 1 year.

(f) The operator shall ensure that all non-permissible electronic surveying equipment is serviced according to the manufacturer's recommendations. Dates of service shall be recorded in the equipment's logbook and shall include a description of the work performed.

(g) The non-permissible surveying equipment to be used in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces shall not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of the Decision and Order.

(h) Non-permissible surveying equipment shall not be used if methane is detected in concentrations at or above 1.0 percent methane. When 1.0 percent or more of methane is detected while the non-permissible surveying equipment is being used, the equipment shall be de-energized immediately and the non-permissible electronic equipment withdrawn outby the last open crosscut, out of the return, or more than 150 feet from pillar workings or longwall faces. All requirements of 30 CFR 75.323 shall be complied with prior to entering in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces.

(i) As an additional safety check, prior to setting up and energizing non-permissible electronic surveying equipment in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces,

the surveyor(s) shall conduct a visual examination of the immediate area for evidence that the area appears to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated float coal dust is observed, the equipment shall not be energized until sufficient rock dust has been applied and/or the accumulations of float coal dust have been removed. If non-permissible electronic surveying equipment is to be used in an area that has not been rockdusted within 40 feet of a working face where a continuous mining machine is used to extract coal, the area shall be rock-dusted prior to energizing the electronic surveying equipment.

(j) All hand-held methane detectors shall be MSHA-approved and maintained in permissible and proper operating condition as defined by 30 CFR 75.320. All methane detectors shall provide visual and audible warnings when methane is detected at or above

1.0 percent.

(k) Prior to energizing any of the nonpermissible surveying equipment in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces, methane tests shall be made in accordance with 30 CFR 75.323(a).

(l) All areas to be surveyed must be pre-shifted according to 30 CFR 75.360 prior to surveying. If the area was not pre-shifted, a supplemental examination according to 30 CFR 75.361 shall be performed before any non-certified person enters the area. If the area has been examined according to 30 CFR 75.360 or 30 CFR 75.361, additional examination is not required.

(m) A qualified person as defined in 30 CFR 75.151 shall continuously monitor for methane immediately before and during the use of non-permissible surveying equipment in or inby the last open crosscut, in the return, or within 150 feet of pillar workings or longwall faces. A second person in the surveying crew, if there are two people in the crew, shall also continuously monitor for methane. That person shall be a qualified person as defined in 30 CFR 75.151 or be in the process of being trained to be a qualified person but have yet to "make such tests for a period of 6 months" as required by 30 CFR 75.150. Upon completion of the 6month training period, the second person on the surveying crew shall become qualified in order to continue on the surveying crew. If the surveying crew consists of only one person, they shall monitor for methane with two separate devices.

(n) Batteries contained in the surveying equipment shall be changed out or charged in intake air outby the last open crosscut, out of the return, and more than 150 feet away from pillar workings or the longwall face. Replacement batteries for the electronic surveying equipment shall be carried only in the electronic equipment carrying case spare battery compartment. Before each surveying shift, all batteries for the electronic surveying equipment shall be charged sufficiently that they are not expected to be replaced on that shift.

(o) When using non-permissible electronic surveying equipment in or inby the last open crosscut, in the return, or within 150 feet of the pillar workings or longwall faces, the surveyor shall confirm by measurement or by inquiry of the person in charge of the section that the air quantity on the section, on that shift, in the last open crosscut is at least the minimum quantity required by the mine's ventilation plan.

(p) Personnel engaged in the use of surveying equipment shall be properly trained to recognize the hazards and limitations associated with the use of surveying equipment in areas where

methane could be present.

(q) All members of the surveying crew shall receive specific training on the terms and conditions of the Decision and Order before using non-permissible electronic equipment in or inby the last open crosscut, in the return, or within 150 feet of the pillar workings or longwall face. A record of the training shall be kept with the other training

(r) Within 60 days after any granted Decision and Order becomes final, the operator shall submit proposed revisions for its approved 30 CFR part 48 training plans to the Coal Mine Safety and Health District Manager. These proposed revisions shall specify initial and refresher training regarding the terms and conditions of the Decision and Order. When training is conducted on the terms and conditions of the Decision and Order, a MSHA Certificate of Training (Form 5000-23) shall be completed and shall include comments indicating it was surveyor training.

(s) The operator shall replace or retire from service any electronic surveying instrument acquired prior to December 31, 2004, within 1 year of the Decision and Order becoming final. Within 3 years of the date the Decision and Order becomes final, the operator shall replace or retire from service any theodolite acquired more than 5 years prior to the date the granted Decision and Order became final and any total station or

other electronic surveying equipment identified in the Decision and Order acquired more than 10 years prior to the date the Decision and Order became final. After 5 years, the operator shall maintain a cycle of purchasing new electronic surveying equipment so that theodolites shall be no older than 5 years from date of manufacture and total stations and other electronic surveying equipment shall be no older than 10 vears from date of manufacture.

(t) The operator is responsible for ensuring that all surveying contractors hired by the operator use electronic equipment in accordance with the requirements of item(s). The conditions of use specified in the Decision and Order shall apply to all non-permissible electronic surveying equipment used in or inby the last open crosscut, in a return, or within 150 feet of pillar workings or longwall faces regardless of whether the equipment is used by the operator or by an independent contractor.

(u) Non-permissible surveying equipment may be used when production is occurring, subject to these conditions:

(1) On a mechanized mining unit (MMU) where production is occurring, non-permissible electronic surveying equipment shall not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as "baloney skins") or curtains.

(2) Production may continue while non-permissible electronic surveying equipment is used if the surveying equipment is used in a separate split of air from where production is occurring.

(3) Non-permissible surveying equipment shall not be used in a split of air ventilating a MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's

approved ventilation plan.

(4) If while surveying a surveyor must disrupt ventilation, the surveyor shall cease surveying and communicate to the section foreman that ventilation must be disrupted. Production shall stop while ventilation is disrupted. Ventilation controls shall be reestablished immediately after the disruption is no longer necessary. Production shall only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans and other applicable laws, standards, or regulations.

(5) Any disruption in ventilation shall be recorded in the logbook required by

the Decision and Order. The logbook shall include a description of the nature of the disruption, the location of the disruption, the date and time of the disruption, the date and time the surveyor communicated the disruption to the section foreman, the date and time production ceased, the date and time ventilation was reestablished, and the date and time production resumed.

(6) All surveyors, section foremen, section crew members, and other personnel who will be involved with or affected by surveying operations shall receive training in accordance with 30 CFR 48.7 on the requirements of the Decision and Order within 60 days of the date the Decision and Order becomes final. Such training shall be completed before any non-permissible surveying equipment can be used while production is occurring. The operator shall keep a record of such training and provide it to MSHA upon request.

(7) The operator shall provide annual retraining to all personnel who will be involved with or affected by surveying operations in accordance with 30 CFR 48.8. The operator shall train new miners on the requirements of the Decision and Order in accordance with 30 CFR 48.5 and shall train experienced miners, as defined in 30 CFR 48.6, on the requirements of the Decision and Order in accordance with 30 CFR 48.6. The operator shall keep a record of such training and provide it to MSHA upon request.

The petitioner asserts that the alternative method proposed will at all times guarantee no less than the same measure of protection afforded the miners under the mandatory standard.

Song-ae Aromie Noe,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2022–24671 Filed 11–10–22; 8:45 am] **BILLING CODE 4520–43–P**

NUCLEAR REGULATORY COMMISSION

[NRC-2021-0162]

Safety Review of Light-Water Power Reactor Construction Permit Applications

AGENCY: Nuclear Regulatory Commission.

ACTION: Interim staff guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Interim Staff Guidance (ISG) "Safety Review of Light-Water Power Reactor Construction Permit Applications" to clarify existing guidance and to assist the NRC staff in

determining whether an application to construct a light-water power reactor (LWR) facility meets the minimum requirements to issue a construction permit (CP). The NRC anticipates the submission of power reactor CP applications in the next few years based on preapplication engagement initiated by several prospective applicants. This guidance is applicable to all applicants for a CP for a light-water power reactor but not to non-LWR applicants or those following the Advanced Reactor Content of Application Project (ARCAP) guidance to the extent the guidance is issued as final and is relevant to the application from a technical and regulatory perspective.

DATES: This guidance is effective on December 14, 2022.

ADDRESSES: Please refer to Docket ID NRC–2021–0162 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-2021-0162. Address questions about Docket IDs in Regulations.gov to Stacy Schumann; telephone: 301-415-0624; email: Stacy.Schumann@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 final ISG for the "Safety Review of Light-Water Power Reactor Construction Permit Applications" is available in ADAMS under Package Accession No. ML22189A097.
- NRC's PDR: You may examine and purchase copies of public documents, by appointment, at the NRC's Public Document Room (PDR), Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Carolyn Lauron, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415– 2736, email: Carolyn.Lauron@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On December 14, 2021 (86 FR 71101) and May 6, 2022, (87 FR 27195), the staff requested public comments on the draft ISG, DNRL-ISG-2022-XX, "Safety Review of Light-Water Power-Reactor Construction Permit Applications." The NRC issued the draft ISG in anticipation of the submission of power-reactor CP applications within the next few years based on preapplication engagement initiated by several prospective applicants. The review of these applications falls within the two-step licensing process under part 50 of title 10 of the Code of Federal Regulations (10 CFR), "Domestic Licensing of Production and Utilization Facilities," and involves the issuance of a CP before an operating license (OL).

The NRC last issued a power reactor CP in the 1970s. Most recently, the NRC issued combined construction and operating licenses (combined licenses (COLs)) for power reactors through the one step licensing process under 10 CFR part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," using the guidance in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition" (https:// www.nrc.gov/reading-rm/doccollections/nuregs/staff/sr0800/cover/ index.html); and Regulatory Guide (RG) 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)," issued June 2007 (ADAMS Package Accession No. ML070720184). The NRC has periodically updated some of the standard review plan (SRP) guidance and issued Revision 1 to RG 1.206, "Applications for Nuclear Power Plants," in October 2018 (ADAMS Package Accession No. ML18131A181).

The licensing process under 10 CFR part 50 allows an applicant to begin construction with preliminary design information instead of the final design required for a COL under 10 CFR part 52. Although the two-step licensing process provides flexibility and allows a more limited safety review before construction, the design has less finality before the applicant commits to construction of the facility. The final safety analysis report (FSAR) submitted with the OL application should describe in detail the final design of the facility as constructed; identify the changes from the criteria, design, and bases in

the CP preliminary safety analysis report (PSAR); and discuss the bases for, and safety significance of, the changes from the PSAR. Before issuing an OL, the NRC staff will review the applicant's final design in the FSAR to determine whether all the Commission's safety requirements have been met.

The SRP contains the NRC staff review guidance for light-water power reactor applications submitted under 10 CFR part 50 or 10 CFR part 52. In addition to the CP review guidance in the SRP, RG 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Revision 3, issued November 1978 (ADAMS Package Accession No. ML011340122), offers some insights on the level of detail that is required for the PSAR in support of the CP application, but these insights may be limited to the degree that the guidance does not account for subsequent requirements, NRC technical positions, or advances in technical knowledge. Regulatory Guide 1.206 provides guidance for 10 CFR part 52 applications, including for early site permits and COLs, and includes insights on the level of detail needed for final design information if the CP applicant chooses to provide such information. The final ISG discusses the use of these guidance documents and supplements the guidance in the SRP.

The NRC recently issued CPs for two nonpower production and utilization facilities—SHINE Medical Technologies, Inc., and Northwest Medical Isotopes, LLC. Some of the lessons learned from these reviews are applicable to the review of powerreactor CP applications, as discussed in the final ISG. The final ISG also discusses other issues pertinent to the safety review of CP applications for light-water power reactors, including the benefits accruing from preapplication engagement, the relationship between the CP and OL reviews, the NRC's approach for reviewing applications incorporating prior NRC approvals, the potential effect of ongoing regulatory activities on CP reviews, and licensing requirements for source, byproduct, and special nuclear material.

The comments received by the NRC on the draft ISG are identified, summarized, and considered in Appendix C, "Analysis of Public Comments on Draft Interim Staff Guidance DNRL—ISG—2022—XX, Safety Review of Light-Water Power-Reactor Construction Permit Applications" (ADAMS Accession No. ML22189A100).

II. Backfitting, Forward Fitting, and Issue Finality

This ISG provides guidance for the NRC staff review of light-water power reactor construction permit applications. Issuance of this final ISG would not constitute backfitting as defined in 10 CFR 50.109 (the Backfit Rule) and as described in NRC Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests"; would not affect the issue finality of an approval under 10 CFR part 52; and would not constitute forward fitting as that term is defined and described in Management Directive 8.4. The staff's position is based upon the following considerations:

The final ISG positions would not constitute backfitting or forward fitting or affect issue finality, inasmuch as the ISG would be internal guidance to NRC staff. The ISG provides interim guidance to the staff on how to review an application for NRC regulatory approval in the form of licensing. Changes in internal staff guidance, without further NRC action, are not matters that meet the definition of backfitting or forward fitting or affect the issue finality of a Part 52 approval.

Backfitting and issue finality—with certain exceptions discussed in this section—do not apply to current or future CP applicants. CP applicants and potential CP applicants are not, with certain exceptions, the subject of either the Backfit Rule or any issue finality provisions under 10 CFR part 52. This is because neither the Backfit Rule nor the issue finality provisions of 10 CFR part 52 were intended to apply to every NRC action that substantially changes the expectations of current and future applicants. The exceptions to the general principle, as applicable to guidance for CP applications, are whenever a 10 CFR part 50 CP applicant references a license (e.g., an early site permit) or an NRC regulatory approval (e.g., a design certification rule) (or both) for which specified issue finality provisions apply. The NRC staff does not currently intend to impose the positions represented in this ISG in a manner that constitutes backfitting or is inconsistent with any issue finality provision of 10 CFR part 52. If in the future the NRC staff seeks to impose positions stated in this ISG in a manner that would constitute backfitting or be inconsistent with these issue finality provisions, the NRC staff must make the requisite showing as set forth in the Backfit Rule or address the regulatory criteria set forth in the applicable issue finality provision, as applicable, that

would allow the staff to impose the position.

Forward fitting—The Commission's forward fitting policy generally does not apply when an applicant files an initial licensing action for a new facility. Nevertheless, the staff does not, at this time, intend to impose the positions represented in the final ISG in a manner that would constitute forward fitting.

III. Congressional Review Act

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

Dated: November 7, 2022.

For the Nuclear Regulatory Commission.

Bernadine I. Thomson,

Deputy Director, Division of New and Renewed Licenses, Office of Nuclear Reactor Regulation.

[FR Doc. 2022–24663 Filed 11–10–22; 8:45 am]

NUCLEAR REGULATORY COMMISSION

701st Meeting of the Advisory Committee on Reactor Safeguards (ACRS)

In accordance with the purposes of Sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2039, 2232(b)), the Advisory Committee on Reactor Safeguards (ACRS) will hold meetings on November 29–December 2, 2022. The Committee will be conducting meetings that will include some members being physically present at the NRC while other members participate remotely. Interested members of the public are encouraged to participate remotely in any open sessions via MS Teams or via phone at 301-576-2978, passcode 365869959#. A more detailed agenda including the MS Teams link may be found at the ACRS public website at https://www.nrc.gov/reading-rm/doccollections/acrs/agenda/index.html. If you would like the MS Teams link forwarded to you, please contact the Designated Federal Officer as follows: Quynh.Nguyen@nrc.gov, or Lawrence.Burkhart@nrc.gov.

Tuesday, November 29, 2022

1:00 p.m.-1:05 p.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

1:05 p.m.-2:45 p.m.: Draft Guide (DG)-1374, "Criteria for Use of Computers in Safety Systems at Nuclear Power Plants"/Preparation of Reports/ SHINE Topics and Letter Report (Open)—The Committee will have presentations and discussion with representatives from the NRC staff regarding the subject topic.

2:45 p.m.–3:45 p.m.: Committee Deliberation on DG–1374, "Criteria for Use of Computers in Safety Systems at Nuclear Power Plants"/Preparation of Reports (Open)—The Committee will deliberate regarding the subject topic.

3:45 p.m.-5:15 p.m.: SHINE Operating License Application—Final Safety Evaluation Report (Open/Closed)—The Committee will have presentations and discussion with representatives from the NRC staff regarding the subject topic. [Note: Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

5:15 p.m.-6:00 p.m.: Committee Deliberation on SHINE Operating License Application—Final Safety Evaluation Report (Open/Closed)—The Committee will deliberate regarding the subject topic. [Note: Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

Wednesday, November 30, 2022

8:30 a.m.–10:30 a.m.: Kairos Fuel Qualification Methodology Topical Report (Open/Closed)—The Committee will have presentations and discussion with representatives from the NRC staff regarding the subject topic. [Note: Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

10:30 a.m.-11:30 a.m.: Committee Deliberation on Kairos Fuel Qualification Methodology Topical Report (Open/Closed)—The Committee will deliberate regarding the subject topic. [Note: Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

1:00 p.m.-6:00 p.m.: Preparation of Reports (Open)—The Committee will continue its discussion of proposed ACRS reports.

Thursday, December 1, 2022

8:30 a.m.-6:00 p.m.: Preparation of Reports (Open/Closed)—The Committee will continue its discussion of proposed ACRS reports. [NOTE: Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

Friday, December 2, 2022

8:30 a.m.–1:30 p.m.: Future ACRS Activities/Report of the Planning and Procedures Subcommittee and Reconciliation of ACRS Comments and Recommendations/Preparation of Reports (Open/Closed)—The Committee will hear discussion of the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the Full Committee during future ACRS meetings, and/or proceed to preparation of reports as determined by the Chairman. [Note: Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]. [Note: Pursuant to 5 U.S.C. 552b(c)(2), a portion of this meeting may be closed to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACRS.]

1:30 p.m.-6:00 p.m.: Preparation of Reports (Open)—The Committee will continue its discussion of proposed ACRS reports.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on June 13, 2019 (84 FR 27662). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Persons desiring to make oral statements should notify Quynh Nguyen, Cognizant ACRS Staff and the Designated Federal Officer (DFO) (Telephone: 301-415-5844, Email: Quynh.Nguyen@nrc.gov), 5 days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the cognizant ACRS staff if such rescheduling would result in major inconvenience.

An electronic copy of each presentation should be emailed to the cognizant ACRS staff at least one day before the meeting.

In accordance with Subsection 10(d) of Public Law 92–463 and 5 U.S.C. 552b(c), certain portions of this meeting may be closed, as specifically noted above. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Electronic recordings will be permitted only during the open portions of the meeting.

ACRS meeting agendas, meeting transcripts, and letter reports are available through the NRC Public Document Room (PDR) at pdr.resource@nrc.gov, or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System component of NRC's Agencywide Documents Access and Management System, which is accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html or http://www.nrc.gov/reading-rm/doc-collections/#ACRS/.

Dated: November 7, 2022.

Brooke P. Clark,

Secretary of the Commission. [FR Doc. 2022–24658 Filed 11–10–22; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2022-0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of November 14, 21, 28, December 5, 12, 19, 2022. The schedule for Commission meetings is subject to change on short notice. The NRC Commission Meeting Schedule can be found on the internet at: https://www.nrc.gov/public-involve/public-meetings/schedule.html.

PLACE: 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 Anne Silk, NRC Disability Program Specialist, at 301-287-0745, by videophone at 240-428-3217, or by email at Anne.Silk@nrc.gov. Determinations on requests for reasonable accommodation will be made on a case-by-case basis. STATUS: Public.

Members of the public may request to receive the information in these notices electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at Wendy.Moore@nrc.gov or Tyesha.Bush@nrc.gov.

MATTERS TO BE CONSIDERED:

Week of November 14, 2022

There are no meetings scheduled for the week of November 14, 2022.

Week of November 21, 2022—Tentative

There are no meetings scheduled for the week of November 21, 2022.

Week of November 28, 2022—Tentative

There are no meetings scheduled for the week of November 28, 2022.

Week of December 5, 2022—Tentative

Tuesday, December 6, 2022

10:00 a.m. Meeting with the Advisory Committee on the Medical Uses of Isotopes (Public Meeting); (Contact: Celimar Valentin-Rodriguez: 301– 415–7124)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—https://video.nrc.gov/.

Thursday, December 8, 2022

9:00 a.m. Overview of Advanced Reactor Fuel Activities (Public Meeting); (Contact: Stephanie Devlin-Gill, 301–415–5301)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—https://video.nrc.gov/.

Week of December 12, 2022—Tentative

Wednesday, December 14, 2022

10:00 a.m. Briefing on Equal Employment Opportunity, Affirmative Employment, and Small Business (Public Meeting); (Contact: Larniece McKoy Moore: 301–415– 1942)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—https://video.nrc.gov/.

Week of December 19, 2022—Tentative

There are no meetings scheduled for the week of December 19, 2022.

CONTACT PERSON FOR MORE INFORMATION:

For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at Wesley.Held@nrc.gov.

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: November 9, 2022.

For the Nuclear Regulatory Commission. **Wesley W. Held**,

Policy Coordinator, Office of the Secretary. [FR Doc. 2022–24868 Filed 11–9–22; 4:15 pm] BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2023-35 and CP2023-34]

New Postal Products

AGENCY: Postal Regulatory Commission. **ACTION:** Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: Comments are due: November 16, 2022.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at http://www.prc.gov. Those who cannot submit comments electronically should contact the person identified in the FOR FURTHER INFORMATION CONTACT section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT:

David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. IntroductionII. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (http://www.prc.gov). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.1

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. Docket No(s).: MC2023–35 and CP2023–34; Filing Title: USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 80 to Competitive Product List and Notice of Filing Materials Under Seal; Filing Acceptance Date: November 7, 2022; Filing Authority: 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; Public Representative: Kenneth R. Moeller; Comments Due: November 16, 2022.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2022–24686 Filed 11–10–22; 8:45 am] BILLING CODE 7710–FW–P

POSTAL SERVICE

International Product Change—Priority Mail Express International, Priority Mail International & First-Class Package International Service Agreement

AGENCY: Postal ServiceTM.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a Priority Mail Express International, Priority Mail International & First-Class Package

¹ See Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

International Service contract to the list of Negotiated Service Agreements in the Competitive Product List in the Mail Classification Schedule.

DATES: Date of notice: November 14, 2022.

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, (202) 268–7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 3, 2022, it filed with the Postal Regulatory Commission a USPS Request to Add Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 10 to Competitive Product List. Documents are available at www.prc.gov, Docket Nos. MC2023–32 and CP2023–31.

Ruth Stevenson,

Chief Counsel, Ethics and Legal Compliance. [FR Doc. 2022–24622 Filed 11–10–22; 8:45 am] BILLING CODE 7710–12–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Request for Information; Clinical Research Infrastructure and Emergency Clinical Trials; Correction

AGENCY: Office of Science and Technology Policy (OSTP). **ACTION:** Notice of Request for Information (RFI); Correction.

SUMMARY: The Office of Science and Technology Policy published a document in the Federal Register of October 25, 2022, concerning a request for information on Clinical Research Infrastructure and Emergency Clinical Trials. This document corrects an error in that notice.

FOR FURTHER INFORMATION CONTACT: Scott Weaver, 202–456–4444.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of October 25, 2022, in FR Doc. 2022–23110, on page 64823, in the third column, in the first paragraph i., correct the first sentence to read:

i. As described above and in the forthcoming RFI on data capture, we are seeking information on how to create a pilot program enabling clinical trial data collection across a wide variety of trial sites that is easy for health care providers to use and can be scaled up for use in emergency research settings.

Dated: October 8, 2022.

Rachel Wallace,

Deputy General Counsel.
[FR Doc. 2022–24666 Filed 11–10–22; 8:45 am]

BILLING CODE 3270-F1-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-96246; File No. SR-OCC-2022-011]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by The Options Clearing Corporation Concerning Corrections to Its By-Laws

November 7, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Exchange Act" or "Act"),¹ and Rule 19b–4 thereunder,² notice is hereby given that on October 24, 2022, The Options Clearing Corporation ("OCC") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by OCC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

This proposed rule change would amend OCC's By-Laws to (i) correct an inadvertent omission and typographical error in a prior rule filing and (ii) correct an erroneous cross-reference and make other conforming changes consistent with a reorganization effected by another prior proposed rule change. Amendments to OCC's By-Laws and Rules are included in Exhibit 5 of filing SR-OCC-2022-011. Material proposed to be added is marked by underlining, and material proposed to be deleted is marked with strikethrough text. All terms with initial capitalization that are not otherwise defined herein have the same meaning as set forth in the By-Laws and Rules.³

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) Purpose

As a self-regulatory organization ("SRO") that is registered as a covered clearing agency under the Securities Exchange Act of 1934 ("Exchange Act"), as amended,4 and a derivatives clearing organization ("DCO") under the Commodity Exchange Act,⁵ OCC files proposed changes to its rules with the SEC and the Commodity Futures Trading Commission ("CFTC"), including changes to OCC's By-Laws and Rules.⁶ SEC and CFTC regulations require that SROs maintain clear and transparent governance arrangements.7 In order to enhance the clarity and transparency of its By-Laws, OCC is proposing amendments that would (1) correct an inadvertent omission and typographical error introduced by a prior rule filing and (2) correct an erroneous cross-reference and make other conforming changes consistent with a reorganization effected by another prior proposed rule change.

1. Typographical Error Correction

First, OCC has identified an inadvertent omission and typographical error in the text of a prior proposed rule change submitted to the SEC:

- The reference to "Treasurer" in Article IV, Section 2 would be replaced with "Chief Financial Officer," consistent with the intent of the proposed rule change (SR–OCC–2021–010) that amended Section 11 of that Article to address the appointment and responsibilities of a Chief Financial Officer, rather than a Treasurer.8
- OCC would also amend Section 11 of Article IV (Chief Financial Officer), to correct an inadvertent reference to "Chief Compliance Officer," rather than

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ OCC's By-Laws and Rules can be found on OCC's public website: https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.

⁴ 15 U.S.C. 78s.

⁵ 7 U.S.C. 7a–1.

 $^{^6}$ See 17 CFR 240.19b–4 (SRO proposed rule changes filed with the SEC); 17 CFR 40.6 (DCO self-certifications filed with the CFTC).

⁷ See 17 CFR 240.17Ad–22(e)(2)(i) (with respect to governance arrangements of covered clearing agencies); 17 CFR 39.24(a)(1)(iii) [sic] (with respect to DCO governance arrangements).

⁸ See Exchange Act Release No. 93436 (Oct. 27, 2021), 86 FR 60499, 60500 (Nov. 2, 2021) (SR–OCC–2021–010)

the Chief Financial Officer, also consistent with the intent of that proposed rule change.⁹

2. Correcting an Erroneous Cross-Reference

OCC has also identified an erroneous cross-reference to provisions that had been relocated by a prior rule change. Specifically, in a proposed rule change filing concerning the Board's ability to appoint a non-executive Chairman (SR-OCC-2021-007), OCC also revised the provision of the By-Laws concerning the Member Vice Chairman of the Board by relocating the second and third sentence of Article IV, Section 1 (concerning the appointment of the Vice Chairman) to Article IV, Section 7 (concerning the responsibilities of the Vice Chairman).10 By relocating the second sentence of Section 1, the change orphaned a crossreference to that sentence in Article XI, Section 1, which concerns those By-Laws that require stockholder approval to amend.

To correct the erroneous cross reference in Article XI, OCC proposes to move current Article IV, Section 7 in its entirety to Article III, which is the Article that concerns the make-up of the Board and the responsibilities of directors. Article IV, Section 7 would be re-titled "Member Vice Chairman of the Board" 11 and become Article III, Section 9A, consistent with the establishment of Article III, Section 9 (Chairman of the Board) by File No. SR-OCC-2021-007.12 Accordingly, the proposed change would consolidate provisions concerning the appointment and responsibilities of the Chairman and Member Vice Chairman of the Board into a single By-Law Article. In turn, OCC would amend Article XI, Section 1 by deleting the current crossreference to the second sentence of Article IV, Section 1. No additional cross-reference to the relocated provisions would be necessary because Article XI, Section 1 already applies to Article III in its entirety.

(2) Statutory Basis

OCC believes the proposed rule changes are consistent with Section 17A of the Exchange Act and the rules and regulations thereunder. Section 17A(b)(3)(F) 13 of the Exchange Act

requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities and derivatives transactions and protect investors and the public interest. By correcting an inadvertent omission, typographical error, and erroneous cross-references in OCC's By-Laws and Rules, the proposed rule changes facilitate the administration of existing SRO rules designed to promote the prompt and accurate clearance and settlement of securities and derivatives transactions and protect investors and the public interest.

In addition, Rule 17Ad–22(e)(2)(i) requires OCC to maintain written policies and procedures reasonably designed to, among other things, provide for governance arrangements that are clear and transparent. He by correcting errors and applying conforming changes consistent with certain reorganization of the By-Laws effected by SR–OCC–2021–007, the changes discussed above are intended to support the maintenance of OCC's By-Laws and improve the clarity and transparency of the governance arrangements addressed therein.

(B) Clearing Agency's Statement on Burden on Competition

Section 17A(b)(3)(I) of the Exchange Act requires that the rules of a clearing agency not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act. 15 As discussed above, the proposed changes would correct an inadvertent omission, typographical error, and erroneous cross-references, and apply conforming edits to the provisions concerning the Member Vice Chairman consistent with a recent reorganization of the provisions concerning the Chairman. These proposed changes are technical in nature and would not impact the rights or obligations of Clearing Members or other participants in a way that would benefit or disadvantage any participant versus another participant. Accordingly, OCC does not believe that the proposed corrections to its By-Laws and Rules have any impact, or impose any burden, on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments on the proposed rule change were not and are not intended to be solicited with respect to the proposed rule change and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A)(i) 16 of the Act, and Rule 19b-4(f)(1) thereunder,17 the proposed rule change is filed for immediate effectiveness. 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. The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.18

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–OCC-2022-011 on the subject line.

Paper Comments

• Send paper comments in triplicate to Vanessa Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR-OCC-2022-011. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/ 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

⁹ Id.

¹⁰ See Exchange Act Release No. 93102 (Sept. 22, 2021), 86 FR 53718, 53720 (Sept. 28, 2021) (SR–OCC–2021–007).

¹¹ As provided by current Article IV, Section 7, the Vice Chairman of the Board is selected from the Member Directors and is referred to as the "Member Vice Chairman."

¹² Id. at 53719. [sic]

^{13 15} U.S.C. 78q-1(b)(3)(F).

^{14 17} CFR 240.17Ad-22(e)(2)(i).

^{15 15} U.S.C. 78q-1(b)(3)(I).

^{16 15} U.S.C. 78s(b)(3)(A)(i).

^{17 17} CFR 240.19b-4(f)(1).

¹⁸ Notwithstanding its immediate effectiveness, implementation of this rule change will be delayed until this change is deemed certified under CFTC Regulation 40.6.

Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of OCC and on OCC's website at https://www.theocc.com/Company-Information/Documents-and-Archives/ Bv-Laws-and-Rules.

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–OCC–2022–011 and should be submitted on or before December 5, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 19

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–24647 Filed 11–10–22; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-96247; File No. SR-NYSE-2022-48]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Delete Legacy Disciplinary Rules 475, 476, 476A, and 477; Adopt New Rule 2050; and Make Conforming Changes to Rules 2A, 27, 36, 600A, 619, 637, 3170, 8001, 8130, 8320, 9001 and 9217

November 7, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), and Rule 19b–4 thereunder, notice is hereby given that on October 27, 2022, New York Stock Exchange LLC ("NYSE" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to

solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to (1) delete legacy disciplinary Rules 475, 476, 476A, and 477 as obsolete and make conforming changes to Rules 2A, 36, 600A(c), 637, 8001, 8130(d), 8320(d) and 9001, and (2) adopt a new Rule 2050 incorporating the substantive violations currently in Rule 476(a) without change and make conforming changes to Rules 27, 619(h), 3170(C)(3) and 9217. The proposed rule change is available on the Exchange's website at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to (1) delete legacy disciplinary Rules 475, 476, 476A, and 477 as obsolete and make conforming changes to Rules 2A, 36, 600A(c), 637, 8001, 8130(d), 8320(d) and 9001, and (2) adopt a new Rule 2050 incorporating the substantive violations currently in Rule 476(a) without change and make conforming changes to Rules 27, 619(h), 3170(C)(3) and 9217.

Background and Proposed Rule Change

In 2013, the Commission approved the Exchange's adoption of rules relating to investigation, discipline, and sanctions, and other procedural rules, based on the rules of the Financial Industry Regulatory Authority ("FINRA").³ The Exchange represented in that filing that when the transition to the new disciplinary rules was complete and there are no longer any member organizations or persons subject to Rules 475, 476, 476A, and 477, the Exchange would submit a proposed rule change that would delete such rules (except for the listed offenses under NYSE Rule 476(a)). The Exchange represents that the transition to the new disciplinary rules is complete and there are no longer any member organizations or persons subject to Rules 475, 476,

Sanction, and Other Procedural Rules That Are Modeled on the Rules of the Financial Industry Regulatory Authority and To Make Certain Conforming and Technical Changes). Beginning in 2016, the Exchange's affiliates have each in turn adopted the FINRA disciplinary rules. In 2016, NYSE American LLC ("NYSE American") adopted its Rule 8000 and Rule 9000 Series based on the NYSE and FINRA Rule 8000 and Rule 9000 Series. See Securities Exchange Act Release Nos. 77241 (February 26, 2016), 81 FR 11311 (March 3, 2016) (SR-NYSEMKT-2016-30). In 2018, the Commission approved NYSE National, Inc.'s ("NYSE National") adoption of the NYSE National Rule 10.8000 and Rule 10.9000 Series based on the NYSE American and FINRA Rule 8000 and Rule 9000 Series. See Securities Exchange Act Release No. 83289 (May 17, 2018), 83 FR 23968 (May 23, 2018) (SR-NYSENat-2018-02). In 2019, NYSE Arca, Inc. ("NYSE Arca") adopted the NYSE Arca Rule 10.8000 and 10.9000 Series based on the NYSE American Rule 8000 and Rule 9000 Series. See Securities Exchange Act Release No. 85639 (April 12, 2019), 84 FR 16346 (April 18, 2019) (SR-NYSEArca-2019-15). Most recently, NYSE Chicago also adopted investigation, disciplinary, sanction, and other procedural rules modeled on the rules of its affiliates. See Securities Exchange Act Release No. 95020 (June 1, 2022), 87 FR 35034 (June 8, 2022) (SR-NYSECHX-2022-10).

⁴ See Securities Exchange Act Release No. 68678 (January 16, 2013), 78 FR 5213, 5219 (January 24, 2013) (SR–NYSE–2013–02) (Notice of Filing of Proposed Rule Change Adopting Investigation, Disciplinary, Sanction, and Other Procedural Rules That Are Modeled on the Rules of the Financial Industry Regulatory Authority and To Make Certain Conforming and Technical Changes) ("Release No. 68678").

⁵ The Exchange no longer has allied members. The references to "allied member" in Rules 476 and 476A should be to "principal executive." In 2008, the Exchange replaced the term "allied member" with the newly defined category of "principal executive" but did not make corresponding technical changes to Rules 476 and 476A. See Securities Exchange Act Release No. 58549 (September 15, 2008), 73 FR 54444, 54445 (September 19, 2008) (SR-NYSE-2008-80) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment No. 1 Thereto Conforming Certain NYSE Rules to Changes to NYSE Incorporated Rules Recently Filed by the Financial Industry Regulatory Authority, Inc.); Rule 311.18 (defining "principal executive"). See generally Securities and Exchange Act Release No. 58103 (July 3, 2008), 73 FR 40403, 40403-04 (July 14, 2008) (SR-FINRA-2008-036) (Notice of Filing of a Proposed Rule Change Relating to the Incorporated NYSE Rules) (proposing in part to substitute "principal executive" for "allied member" in the Incorporated NYSE Rules); Securities and Exchange Act Release No. 58533 (September 12, 2008), 73 FR 54652 (September 22, 2008) (SR-FINRA-2008-036) (Order Approving Proposed Rule Change Relating to Incorporated NYSE Rules). The Exchange will be submitting a separate rule filing to replace the remaining

^{19 17} CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 69045 (March 5, 2013), 78 FR 15394 (March 11, 2013) (SR-NYSE-2013-02) (Order Approving Proposed Rule Change Adopting Investigation, Disciplinary,

476A, and 477, and that those rules can therefore be deleted as obsolete.

The Exchange proposes conforming changes to Rules 2A (Jurisdiction), 36 (Communications Between Exchange and Members' Offices), 600A(c), and 637 (Failure to Honor Award) that contain references to one or more of the rules proposed to be deleted. The following rules reflecting the transition from the legacy disciplinary rules to the current rule set would be deleted in their entirety: Rule 8130(d) (Retention of Jurisdiction); Rule 8320(d) (Payment of Fines, Other Monetary Sanctions, or Costs; Summary Action for Failure to Pay); Rule 8001 (Effective Date of Rule 8000 Series); and Rule 9001 (Effective Date of Rule 9000 Series).

In connection with the deletion of Rule 476, the Exchange also proposes a new Rule 2050 titled "Other Offenses" that would, consistent with its filing adopting the FINRA disciplinary rules, retain the listed offenses in Rule 476(a)(1)-(11) without substantive change. Proposed Rule 2050 would provide that a member organization or covered person ⁶ violates the provisions of the Rule if it commits any of the enumerated offenses, which would be transposed from Rule 476(a) in the same order and without changes except for Rule 476(a)(8), which is marked "Reserved." The Exchange further proposes conforming changes to the following rules to replace references to Rule 476(a) with Rule 2050: Rule 27 (Regulatory Cooperation); Rule 619(h) (General Provision Governing Subpoenas, Production of Documents, etc.); Rule 3170(C)(3) (Tape Recording of Registered Persons by Certain Firms); and Rule 9217 (Violations Appropriate for Disposition Under Rule 9216(b)).

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b)(5) of the Exchange Act,⁷ 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, 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.

Specifically, the Exchange believes that deletion of the obsolete legacy disciplinary rules now that there are no longer any member organizations or persons subject to those rules, and making conforming changes to the rules referencing those legacy disciplinary rules, would increase the clarity and transparency of the Exchange's rules and remove impediments to and perfect the mechanism of a free and open market by ensuring that persons subject to the Exchange's jurisdiction, regulators, and the investing public could more easily navigate and understand the Exchange Bylaws and rules. The Exchange further believes that the proposed amendments would not be inconsistent with the public interest and the protection of investors because investors will not be harmed and in fact would benefit from increased transparency and clarity, thereby reducing potential confusion.

The Exchange further believes that retaining the substantive offenses in Rule 476(a) without change is designed to prevent fraudulent and manipulative acts and practices by permitting the Exchange to continue to carry out its oversight and enforcement responsibilities with respect to the substantive provisions currently enumerated in Rule 476(a). For the same reasons, retention of those provisions would not be inconsistent with the public interest and the protection of investors.

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 proposed rule change is not intended to address competitive issues but rather is concerned solely with deleting obsolete rules and making related and conforming changes.

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

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 Act ⁸ and subparagraph (f)(6) of Rule 19b–4 thereunder. ⁹

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. 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-NYSE-2022-48.

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–NYSE–2022–48. 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

references to "allied member" in its rules with "principal executive."

⁶NYSE Rule 9120(g) defines "covered person" to mean a "member, principal executive, approved person, registered or non-registered employee of a member organization, or other person (excluding a member organization) subject to the jurisdiction of the Exchange." The term was drafted to appropriately capture all persons subject to the legacy disciplinary rules and preserve the Exchange's scope of jurisdiction at the time the Rule 8000 and Rule 9000 Series were adopted. See Release No. 68678, 78 FR 5213 at 5219. Under NYSE Rule 2(a), the term "member" means a natural person associated with a member organization who has been approved by the Exchange and designated by such member organization to effect transactions on the floor of the Exchange or any facility thereof. See id.

^{7 15} U.S.C. 78f(b)(5).

⁸ 15 U.S.C. 78s(b)(3)(A).

⁹¹⁷ CFR 240.19b–4(f)(6). In addition, Rule19b–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.

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-NYSE-2022-48, and should be submitted on or before December 5, 2022

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 10

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–24648 Filed 11–10–22; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96252; File No. SR– NYSEARCA–2022–74]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the NYSE Arca Options Fee Schedule

November 7, 2022.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 ("Act") ² and Rule 19b–4 thereunder, ³ notice is hereby given that, on October 31, 2022, NYSE Arca, Inc. ("NYSE Arca" 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.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the NYSE Arca Options Fee Schedule ("Fee Schedule') regarding the Ratio Threshold Fee. The Exchange proposes to implement the fee change effective November 1, 2022. The proposed rule 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 extend the waiver of the Ratio Threshold Fee that was implemented in connection with the Exchange's migration to the Pillar platform.⁴ The Exchange proposes to implement the rule change on November 1, 2022.

The Ratio Threshold Fee is based on the number of orders entered as compared to the number of executions received in a calendar month and is intended to deter OTP Holders from submitting an excessive number of orders that are not executed.⁵ Because order to execution ratios of 10,000 to 1

or greater have the potential residual effect of exhausting system resources, bandwidth, and capacity, such ratios may create latency and impact other OTP Holders' ability to receive timely executions.⁶ In connection with the Exchange's migration to the Pillar platform, the Exchange implemented a waiver of the Ratio Threshold Fee (the "Waiver") that took effect beginning in the month in which the Exchange began its migration to the Pillar platform and would remain in effect for the three months following the month during which the Exchange completed its migration to the Pillar platform. As the Exchange completed the migration in July 2022, the Waiver is currently due to expire on October 31, 2022.

The Exchange now proposes to extend the Waiver for an additional three months. The Exchange believes that extending the Waiver would allow the Exchange additional time to continue to work with OTP Holders to monitor traffic rates and order to execution ratios, without imposing a financial burden on OTP Holders based on their order to execution ratios. The extension of the Waiver would also allow the Exchange to continue to evaluate system performance as OTP Holders continue to adapt to trading on the Pillar platform. The Exchange thus proposes to modify the Fee Schedule to provide that the Waiver would extend for the six months following the month in which the Exchange completed its migration to the Pillar platform (i.e., until January 31, 2023).7

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁸ in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,⁹ in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Rule Change Is Reasonable

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities

^{10 17} CFR 200.30-3(a)(12).

^{1 15} U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

^{3 17} CFR 240.19b-4.

⁴ See Securities Exchange Act Release No. 94095 (January 28, 2022), 87 FR 6216 (February 3, 2022) (SR-NYSEArca-2022-04) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE Arca Options Fee Schedule).

⁵ See Fee Schedule, RATIO THRESHOLD FEE; see also Securities Exchange Act Release No. 60102 (June 11, 2009), 74 FR 29251 (June 19, 2009) (SR–NYSEArca–2009–50).

 $^{^6}$ See id.

⁷ See proposed Fee Schedule, RATIO THRESHOLD FEE.

^{8 15} U.S.C. 78f(b).

^{9 15} U.S.C. 78f(b)(4) and (5).

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." ¹⁰

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. 11 Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in September 2022, the Exchange had less than 11% market share of executed volume of multiplylisted equity and ETF options trades. 12

The Exchange believes that the evershifting 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 fees. In response to this competitive environment and to adapt to extenuating circumstances, the Exchange has previously waived fees on a temporary basis.¹³

The Exchange believes that the proposed extension of the Waiver is reasonable because it is designed to lessen the impact of the migration on OTP Holders and would allow OTP Holders to continue to adjust to trading on the Pillar platform without incurring excess Ratio Threshold Fees while the Exchange continues to evaluate Pillar system performance. To the extent the proposed rule change encourages OTP

Holders to maintain their trading activity on the Exchange, the Exchange believes the proposed change would sustain the Exchange's overall competitiveness and 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 mitigate the impacts of the Pillar migration without affecting its competitiveness.

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 proposed extension of the Waiver is an equitable allocation of fees and credits because the Waiver would continue to apply to all OTP Holders. All OTP Holders would thus have the opportunity to continue adjusting to the Pillar platform without incurring Ratio Threshold Fees, while the Exchange continues to evaluate post-migration system performance. Thus, the Exchange believes the proposed rule change would continue to mitigate the impact of the migration process for all market participants on the Exchange, thereby sustaining market-wide quality.

The Proposed Rule Change Is Not Unfairly Discriminatory

The Exchange believes the proposed extension of the Waiver is not unfairly discriminatory because it would apply to all OTP Holders on an equal and nondiscriminatory basis. The Waiver, as proposed, would permit all OTP Holders to continue adapting to the Pillar platform, without incurring additional fees based on their monthly order to execution ratios, while the Exchange continues to evaluate postmigration system performance. The Exchange thus believes that the proposed change would support continued trading opportunities for all market participants, thereby promoting just and equitable principles of trade, removing impediments to and perfecting the mechanism of a free and open market and a national market system and, in general, protecting investors and the public interest. Finally, the Exchange believes that it

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed change 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." 14

Intramarket Competition. The Exchange does not believe the proposed extension of the Waiver would impose any burden on intramarket competition that is not necessary or appropriate because it would apply equally to all OTP Holders. All OTP Holders would continue to be eligible for the Waiver for an additional three months while the Exchange continues to assess system performance following the migration to Pillar.

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 publiclyavailable 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. 15 Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in September 2022, the Exchange had less than 11% market share of executed volume of multiplylisted equity and ETF options trades. 16

Continued

¹⁰ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7–10–04) ("Reg NMS Adopting Release").

¹¹ 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/Market-Data-Reports/Volume-and-Open-Interest/Monthly-Weekly-Volume-Statistics.

¹² Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of equity-based ETF options, *see id.*, the Exchange's market share in equity-based options decreased from 12.43% for the month of September 2021 to 10.84% for the month of September 2022.

¹³ See, e.g., Securities Exchange Act Release No. 88596 (April 8, 2020), 85 FR 20796 (April 14, 2020) (SR-NYSEArca-2020-29) (waiving Floor related fees in connection with COVID-19 precautionary measures).

 $^{^{14}\,}See$ Reg NMS Adopting Release, supra note 10, at 37499.

¹⁵ 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/Market-Data-Reports/Volume-and-Open-Interest/Monthly-Weekly-Volume-Statistics.

¹⁶ Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of equity-based ETF options, see id., the Exchange's market share in equity-based options increased decreased from 12.43% for the

The Exchange does not believe the proposed rule change would impose any burden on intermarket competition that is not necessary or appropriate because the Exchange operates in a highly competitive market in which market participants can readily choose to send their orders to other exchanges if they deem fee levels at those other venues to be more favorable. The Exchange believes that fees to prevent excessive use of Exchange systems are constrained by the robust competition for order flow among exchanges. The Exchange believes that the proposed extension of the Waiver would continue to make the Exchange a competitive venue for order execution by enabling OTP Holders to maintain trading activity without incurring fees based on their monthly order to execution ratios, thus facilitating OTP Holders' continued adjustment to the Pillar platform and permitting the Exchange additional time to evaluate post-migration system performance.

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) ¹⁷ of the Act and subparagraph (f)(2) of Rule 19b–4 ¹⁸ 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) 19 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

month of September 2021 to 10.84% for the month of September 2022.

arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@* sec.gov. Please include File Number SR–NYSEARCA–2022–74 on the subject line

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR-NYSEARCA-2022-74. 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-NYSEARCA-2022-74, and should be submitted on or before December 5, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022-24653 Filed 11-10-22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-96248; File No. SR-NASDAQ-2022-060]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Specify an Implementation Timeframe for the Introduction of Enhanced Anti-Internalization Functionality

November 7, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b–4 thereunder,² notice is hereby given that on October 31, 2022, 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 specify an implementation timeframe for the introduction of enhanced anti-internalization functionality.

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.

¹⁷ 15 U.S.C. 78s(b)(3)(A).

^{18 17} CFR 240.19b-4(f)(2).

¹⁹ 15 U.S.C. 78s(b)(2)(B).

^{20 17} CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to specify an implementation timeframe for the introduction of enhanced anti-internalization functionality. The Exchange previously filed ³ a rule change to enhance the anti-internalization functionality available on the Exchange by giving market participants the flexibility to choose to have this protection apply to market participants under Common Ownership.⁴

By way of background, antiinternalization, also known as selfmatch prevention, is an optional feature available on the Exchange that currently (1) prevents two orders with the same Market Participant Identifier (MPID) from executing against each other, or (2) prevents two orders entered through a specific order entry port from executing against each other (in the case of market participants using the OUCH order entry protocol). The enhanced antiinternalization functionality, as proposed in SR-NASDAQ-2022-056,5 would permit market participants to direct that quotes/orders entered into the System not execute against quotes/ orders entered across MPIDs that are under Common Ownership.

The previous rule filing 6 to enhance the anti-internalization functionality available on the Exchange did not specify an implementation date. The Exchange proposes to establish an implementation timeframe that extends beyond 30 days after the date of filing of SR-NASDAQ-2022-056.7 Specifically, the Exchange proposes to implement the enhanced antiinternalization functionality no later than the First Quarter of 2023. The delay would provide the Exchange additional time to develop and test this functionality. The Exchange will issue an Equities Trader Alert to provide notification of the change and relevant implementation date prior to introducing the new functionality.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b)

of the Act,8 in general, and furthers the objectives of Section 6(b)(5) of the Act,9 in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The change in anti-internalization functionality will enhance self-trade protections provided to market participants and the Exchange desires to rollout the anti-internalization functionality at a later date to allow sufficient time to develop and test this functionality. As proposed herein, the Exchange will offer the enhanced antiinternalization functionality no later than the First Quarter of 2023.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impact the intense competition that exists in the equities markets. The Exchange does not believe that the proposed delay will impose any significant burden on intermarket competition as it does not impact the ability of other markets to offer or not offer competing functionality. The Exchange does not believe that the proposed rule change will impose any burden on intra-market competition because all participants uniformly will not be able to take advantage of the enhanced antiinternalization functionality until it is implemented. The Exchange intends to offer the optional, enhanced antiinternalization functionality no later than the First Quarter of 2023.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act ¹⁰ and Rule 19b– 4(f)(6) thereunder.¹¹

A proposed rule change filed under Rule $19b-4(f)(6)^{12}$ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),13 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. Waiver of the operative delay would allow the Exchange to extend the implementation timeframe of SR-NASDAQ-2022-056 prior to the scheduled effective date for SR-NASDAO-2022-056, which is scheduled to become effective on November 5, 2022. The Exchange states that extending the implementation timeframe prior to the currently scheduled effective date will ensure that the Exchange's rules continue to properly reflect the delay of the enhanced anti-internalization functionality, which will not be available on the Exchange by the currently scheduled date. The Exchange further states that delaying the introduction of the enhanced antiinternalization functionality will provide additional time to develop and test this functionality. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.14

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings

³ Securities Exchange Act Release No. 96069 (October 13, 2022), 87 FR 63558 (October 19, 2022).

⁴ The Exchange previously proposed to define "Common Ownership" under Equity 4, Rule 4757 to mean participants under 75% common ownership or control. *See id.*

⁵ Supra note 4.

⁶ Id.

⁷ Id.

^{8 15} U.S.C. 78f(b).

^{9 15} U.S.C. 78f(b)(5).

¹⁰ 15 U.S.C. 78s(b)(3)(A).

¹¹ 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.

^{12 17} CFR 240.19b-4(f)(6).

^{13 17} CFR 240.19b-4(f)(6)(iii).

¹⁴ For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

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-2022-060 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-2022-060. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NASDAQ-2022-060 and should be submitted on or before December 5, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁵

J. Matthew DeLesDernier,

Deputy Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-96251; File No. SR-PEARL-2022-35]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Withdrawal of Proposed Rule Change To Amend the MIAX PEARL Options Fee Schedule To Remove Certain Credits

November 7, 2022.

On September 1, 2022, MIAX PEARL, LLC (''MIAX Pearl'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ¹ and Rule 19b–4 thereunder,² a proposed rule change to remove certain credits. The proposed rule change was published for comment in the **Federal Register** on September 20, 2022.³

On October 25, 2022, MIAX Pearl withdrew the proposed rule change (SR-PEARL-2022-35).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 4

J. Matthew DeLesDernier,

Deputy Secretary.

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BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-96250; File No. SR-PEARL-2022-46]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX PEARL Options Fee Schedule To Remove the Monthly Volume Credit

November 7, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b–4 thereunder,² notice is hereby given that on November 2, 2022, MIAX PEARL, LLC ("MIAX Pearl" or "Exchange") filed with the Securities and Exchange Commission ("Commission") a proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Pearl Options Fee Schedule (the "Fee Schedule") to remove the "Monthly Volume Credit" from the Fee Schedule.

The text of the proposed rule change is available on the Exchange's website at http://www.miaxoptions.com/rule-filings/pearl at MIAX Pearl's principal office, 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 commenced operations in February 2017 ³ and adopted its initial fee schedule. ⁴ In 2018, as the Exchange's market share increased, ⁵ the Exchange adopted a Monthly Volume Credit ⁶ to continue to attract order flow

^{15 17} CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

 $^{^3\,}See$ Securities Exchange Act Release No. 95775 (September 14, 2022), 87 FR 57544.

⁴¹⁷ CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See MIAX PEARL Successfully Launches Trading Operations, dated February 6, 2017, available at https://www.miaxoptions.com/sites/ default/files/alert-files/MIAX_Press_Release_ 02062017.pdf.

⁴ See Securities Exchange Act Release No. 80061 (February 17, 2017), 82 FR 11676 (February 24, 2017) (SR–PEARL–2017–10).

⁵The Exchange experienced a monthly average trading volume in equity options of 3.94% for the month of March 2018. See Market at a Glance, available at www.miaxoptions.com (last visited November 2, 2022).

⁶ See Securities Exchange Act Release No. 82867 (March 13, 2018), 83 FR 12044 (March 19, 2018) (SR–PEARL–2018–07).

and increase membership by lowering the costs for Members. The Exchange believes that the Monthly Volume Credit has served its purpose of incentivizing market participants to trade on the Exchange as the Exchange's market share continues to grow and increase since the credits were established. Therefore, the Exchange now proposes to remove the Monthly Volume Credit from the Fee Schedule.

The Exchange proposes to amend the Definitions section of the Fee Schedule to delete the definition and remove the credits applicable to the Monthly Volume Credit for Members. The Exchange established the Monthly Volume Credit in 2018 9 to encourage Members to send increased Priority Customer 10 order flow to the Exchange. which the Exchange applied as a metric to the assessment of non-transaction fees for that Member. During the period when the Monthly Volume Credit was in effect (as further described below), the Exchange applied a different Monthly Volume Credit depending on whether the Member connected to the Exchange via the FIX Interface 11 or MEO Interface. 12 During the period when the Monthly Volume Credit was in effect, the Exchange assessed the Monthly Volume Credit to each Member that had executed Priority Customer volume along with that of its affiliates,13

not including Excluded Contracts,¹⁴ of at least 0.30% of MIAX Pearl-listed Total Consolidated Volume ("TCV"),¹⁵ as set forth in the following table:

Type of member connection	Monthly volume credit	
Member that connects via the FIX Interface	\$250	
the MEO Interface	1,000	

If a Member connected via both the MEO Interface and FIX Interface and qualified for the Monthly Volume Credit based upon its Priority Customer volume, the greater Monthly Volume Credit would apply to such Member. During the periods when the Monthly Volume Credit was in effect, the Monthly Volume Credit was a single, once-per-month credit towards the aggregate monthly total of non-transaction fees assessable to a Member.

The Exchange proposes to amend the Definitions section of the Fee Schedule to delete the definition and remove the Monthly Volume Credit. The Exchange established the Monthly Volume Credit when it first launched operations to

Maker (who does not otherwise have a corporate affiliation based upon common ownership with an EEM) that has been appointed by an EEM and an "Appointed EEM" is an EEM (who does not otherwise have a corporate affiliation based upon common ownership with a MIAX Pearl Market Maker) that has been appointed by a MIAX Pearl Market Maker, pursuant to the following process. A MIAX Pearl Market Maker appoints an EEM and an EEM appoints a MIAX Pearl Market Maker, for the purposes of the Fee Schedule, by each completing and sending an executed Volume Aggregation Request Form by email to membership@ miaxoptions.com no later than 2 business days prior to the first business day of the month in which the designation is to become effective. Transmittal of a validly completed and executed form to the Exchange along with the Exchange's acknowledgement of the effective designation to each of the Market Maker and EEM will be viewed as acceptance of the appointment. The Exchange will only recognize one designation per Member. A Member may make a designation not more than once every 12 months (from the date of its most recent designation), which designation shall remain in effect unless or until the Exchange receives written notice submitted 2 business days prior to the first business day of the month from either Member indicating that the appointment has been terminated. Designations will become operative on the first business day of the effective month and may not be terminated prior to the end of the month. Execution data and reports will be provided to both parties. See the Definitions Section of the Fee Schedule.

encourage Members to increase their order flow by providing a credit to those that exceeded a volume threshold. The Exchange believes that the Exchange's existing Priority Customer rebates and fees will continue to allow the Exchange to remain highly competitive and continue to attract order flow and maintain market share even without the Monthly Volume Credit.¹⁶

Implementation and Procedural History

The proposed rule change will be immediately effective. The Exchange initially filed this proposal to remove the Monthly Volume Credit (and monthly credits associated with Trading Permits) on July 1, 2021, with the proposed fees being immediately effective.¹⁷ In that proposal, the Exchange also proposed to increase its Trading Permit fees. Between August 2021 and September 2022, the Exchange withdrew and refiled the proposed rule change, each time to meaningfully attempt to provide additional justification for the proposed fee changes, provide enhanced details regarding the Exchange's cost methodology or to supplement its competition based arguments. 18 The Commission received three comment letters from one commenter on the various filings. 19 On October 25, 2022, the Exchange withdrew its latest proposal and submitted a revised proposal to only remove the Monthly Volume Credit (SR–PEARL–2022–44, which was not noticed by the Commission). On November 2, 2022, the Exchange withdrew SR-PEARL-2022-44 and now resubmits a revised proposal to only remove the Monthly Volume Credit.

⁷The term "Member" means an individual or organization that is registered with the Exchange pursuant to Chapter II of Exchange Rules for purposes of trading on the Exchange as an "Electronic Exchange Member" or "Market Maker." Members are deemed "members" under the Exchange Act. See Exchange Rule 100 and the Definitions Section of the Fee Schedule.

⁸ The Exchange experienced a monthly average trading volume in equity options of 4.35% for the month of October 2022. *See* Market at a Glance, *supra* note 5 (last visited November 2, 2022).

⁹ See supra note 6.

¹⁰ The term "Priority Customer" means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial accounts(s). The number of orders shall be counted in accordance with Interpretation and Policy .01 of Exchange Rule 100. See the Definitions Section of the Fee Schedule and Exchange Rule 100, including Interpretation and Policy .01.

¹¹The term "FIX Interface" means the Financial Information Exchange interface for certain order types as set forth in Exchange Rule 516. See the Definitions Section of the Fee Schedule and Exchange Rule 100.

¹² The term "MEO Interface" or "MEO" means a binary order interface for certain order types as set forth in Rule 516 into the MIAX Pearl System. See the Definitions Section of the Fee Schedule and Exchange Rule 100.

^{13 &}quot;Affiliate" means (i) an affiliate of a Member of at least 75% common ownership between the firms as reflected on each firm's Form BD, Schedule A, or (ii) the Appointed Market Maker of an Appointed EEM (or, conversely, the Appointed EEM of an Appointed Market Maker). An "Appointed Market Maker" is a MIAX Pearl Market

¹⁴ "Excluded Contracts" means any contracts routed to an away market for execution. *See* the Definitions Section of the Fee Schedule.

^{15 &}quot;TCV" means total consolidated volume calculated as the total national volume in those classes listed on MIAX Pearl for the month for which the fees apply, excluding consolidated volume executed during the period of time in which the Exchange experiences an Exchange System Disruption (solely in the option classes of the affected Matching Engine). See the Definitions Section of the Fee Schedule.

¹⁶ See, generally, Fee Schedule, Section 1)a).

¹⁷ See Securities Exchange Act Release No. 92366 (July 9, 2021), 86 FR 37379 (SR-PEARL-2021-32).

¹⁸ See Securities Exchange Act Release Nos. 92797 (August 27, 2021), 86 FR 49399 (September 2, 2021) (SR-PEARL-2021-32) ("Suspension Order 1"); 93555 (November 10, 2021), 86 FR 64254 (November 17, 2021) (SR-PEARL-2021-54); 93895 (January 4, 2022), 87 FR 1217 (January 10, 2022) (SR-PEARL-2021-59); 94287 (February 18, 2022), 87 FR 10837 (February 25, 2022) (SR-PEARL-2022-05) ("Suspension Order 2"); 94696 (April 12, 2022), 87 FR 22987 (April 18, 2022) (SR-PEARL-2022-09); 94993 (May 26, 2022), 87 FR 33518 (June 2, 2022) (SR-PEARL-2022-23); SR-PEARL-2022-28; 95419 (August 4, 2022), 87 FR 48702 (August 10, 2022 (SR-PEARL-2022-30); 95775 (September 15, 2022), 87 FR 57544 (September 20, 2022) (SR– PEARL-2022-35).

¹⁹ See Letters from Richard J. McDonald, Susquehanna International Group, LLC ("SIG"), to Vanessa Countryman, Secretary, Commission, dated September 28, 2021 and March 15, 2022, and Letter from Brian Sopinsky, General Counsel, SIG, to Vanessa Countryman, Secretary, Commission, dated May 9, 2022.

2. Statutory Basis

The Exchange believes that its proposal to amend the Fee Schedule is consistent with Section 6(b) of the Act 20 in general, and furthers the objectives of Section 6(b)(4) of the Act 21 in particular, in that it is an equitable allocation of reasonable dues, fees and other charges among its members and issuers and other persons using its facilities. The proposed changes to the Fee Schedule are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for order flow, which constrains its pricing determinations. The fact that the market for order flow is competitive has long been recognized by the courts. In NetCoalition v. Securities and Exchange Commission, the D.C. Circuit stated, "[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers' . ."22

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention to determine prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, 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." 23

The Exchange believes that the evershifting market share among the exchanges from month to month demonstrates that market participants can discontinue or reduce use of certain categories of products and services, terminate an existing membership or determine to not become a new member, and/or shift order flow, in response to

transaction fee changes. For example, on February 28, 2019, the Exchange filed with the Commission a proposal to increase Taker fees in certain Tiers for options transactions in certain Penny classes for Priority Customers and decrease Maker rebates in certain Tiers for options transactions in Penny classes for Priority Customers (which fee was to be effective March 1, 2019).24 The Exchange experienced a decrease in total market share for the month of March 2019, after the proposal went into effect. Accordingly, the Exchange believes that its March 1, 2019, fee change, to increase certain transaction fees and decrease certain transaction rebates, may have contributed to the decrease in MIAX Pearl's market share and, as such, the Exchange believes competitive forces constrain the Exchange's, and other options exchanges, ability to set transaction fees and market participants can shift order flow based on fee changes instituted by the exchanges.

The Exchange believes its proposal to remove the Monthly Volume Credit is reasonable, equitable and not unfairly discriminatory because all market participants will no longer be offered the ability to achieve the extra credits associated with the Monthly Volume Credit for submitting Priority Customer volume to the Exchange. The Exchange believes it is reasonable and equitable to remove the Monthly Volume Credit from the Fee Schedule for business and competitive reasons. The Exchange established the Monthly Volume Credit when it first launched operations to encourage Members to increase their order flow by providing a credit to those that exceeded a volume threshold. The Exchange believes that the Exchange's existing Priority Customer rebates and fees will continue to allow the Exchange to remain highly competitive and continue to attract order flow and maintain market share even without the Monthly Volume Credit.²⁵

The Exchange further believes its proposal to remove the Monthly Volume Credit is reasonable because the Exchange originally adopted the Monthly Volume Credit to attract order flow to increase the Exchange's market share. The Exchange believes that the Monthly Volume Credit has served its purpose of incentivizing market participants to trade on the Exchange as the Exchange's market share continues to grow and increase since the credit

was established.²⁶ Therefore, the Exchange believes it is reasonable to remove the Monthly Volume Credit from the Fee Schedule.

Lastly, the Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act in that it is not designed to permit unfair discrimination between customers, issuers, brokers and dealers because the Monthly Volume Credit will no longer be available to any Member and all Members would now be subject to the same level of non-transaction fees regardless of the amount of Priority Customer volume they execute on the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,²⁷ the Exchange believes that the proposed rule change would not impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange believes the removal of the Monthly Volume Credit will not place certain market participants at a relative disadvantage to other market participants because, in order to attract order flow, the Exchange established this credit to lower the initial fixed cost for Members. The Exchange now believes that it is appropriate to remove this credit in light of the current operating conditions, including the Exchange's overall membership and the current type and amount of volume executed on the Exchange. The Exchange believes that the Exchange's current rebates and fees will still allow the Exchange to remain highly competitive such that the Exchange should continue to attract order flow and maintain market share.28 Lastly, the proposed fee change will not impact intra-market competition because it will apply to all Members equally.

Inter-Market Competition

The Exchange operates in a highly competitive market in which market participants can readily favor one of the 15 competing options venues if they deem fee levels at a particular venue to be excessive. Based on publicly-available information, and excluding index-based options, no single exchange has more than approximately 16%

²⁰ 15 U.S.C. 78f(b).

^{21 15} U.S.C. 78f(b)(4).

 ²² See NetCoalition, 615 F.3d at 539 (D.C. Cir.
 2010) (quoting Securities Exchange Act Release No.
 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR-NYSEArca-2006-21)).

²³ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) ("Regulation NMS Adopting Release").

²⁴ See Securities Exchange Act Release No. 85304 (March 13, 2019), 84 FR 10144 (March 19, 2019) (SR-PEARL-2019-07).

²⁵ See Fee Schedule, Section 1)a).

²⁶ The Exchange experienced a monthly average trading volume in equity options of 4.35% for the month of October 2022. *See* Market at a Glance, *supra* note 5 (last visited November 2, 2022).

^{27 15} U.S.C. 78f(8).

²⁸ See, generally, Fee Schedule, Section 1)a).

market share. Therefore, no exchange possesses significant pricing power regarding memberships or in the execution of multiply-listed equity and exchange-traded fund ("ETF") options order flow. Over the course of 2021 and 2022, the Exchange's market share has fluctuated between approximately 3-6% of the U.S. equity options industry.²⁹ The Exchange is not aware of any evidence that a market share of approximately 3-6% provides the Exchange with anti-competitive pricing power when it comes to competition for memberships. The Exchange believes that the ever-shifting market share among exchanges from month to month demonstrates that market participants can discontinue memberships in response to fee changes. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract and retain memberships on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange responded to comment letters in a prior proposal.³⁰

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,31 and Rule 19b-4(f)(2) 32 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 shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods: Electronic Comments

- Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@ sec.gov*. Please include File Number SR–PEARL–2022–46 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-PEARL-2022-46. 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-PEARL-2022-46 and should be submitted on or before December 5, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 33

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–24651 Filed 11–10–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96249; File No. SR– PEARL–2022–47]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX PEARL Options Fee Schedule To Remove a Monthly Credit Associated With Trading Permit Fees

November 7, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b–4 thereunder,² notice is hereby given that on November 2, 2022, MIAX PEARL, LLC ("MIAX Pearl" or "Exchange") filed with the Securities and Exchange Commission ("Commission") a proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Pearl Options Fee Schedule (the "Fee Schedule") to remove a monthly credit associated with Trading Permit (defined below) fees.

The text of the proposed rule change is available on the Exchange's website at http://www.miaxoptions.com/rule-filings/pearl at MIAX Pearl's principal office, 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.

 $^{^{29}\,}See\,supra$ note 5.

³⁰ See supra note 18.

^{31 15} U.S.C. 78s(b)(3)(A)(ii).

^{32 17} CFR 240.19b-4(f)(2).

^{33 17} CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange commenced operations in February 2017³ and adopted its initial fee schedule that waived fees for Trading Permits 4 to trade on the Exchange.⁵ In 2018, as the Exchange's market share increased,6 the Exchange adopted nominal fees for Trading Permits based on the type of interface used-MEO 7 or FIX 8-and according to the volume-based tier 9 each Member 10 achieved during the month along with that of its Affiliates.¹¹ At the same time, the Exchange adopted a nominal monthly credit known as the "Trading Permit Fee Credit," a \$100 per month credit for Members that connected to the Exchange via both the MEO and FIX Interfaces.12

The Exchange has two types of Members, Electronic Exchange Members

("EEMs") 13 and Market Makers. 14 The Exchange recently filed a proposal with the Commission to amend the calculation and amount of Trading Permit fees assessed to Market Makers, and adopt a flat Trading Permit fee for EEMs, based on the type of interface used, MEO and/or FIX. Pursuant to that proposal, the Exchange moved away from the volume tier-based Trading Permit fee structure for Market Maker Trading Permit fees; instead, Market Makers are assessed Trading Permit fees based upon the number of classes in which the Market Maker was registered to quote on any given day within the calendar month, or upon the class volume percentages set forth in the table in Section 3)b) of the Fee Schedule. 15

The Exchange established the Trading Permit Fee Credit to continue to attract order flow and increase membership by lowering Trading Permit costs for Members. 16 The Exchange adopted the Trading Permit Fee Credit to incentivize market participants to trade on the Exchange and help the Exchange's market share grow.¹⁷ This practice is not uncommon. New exchanges often do not charge fees or offer pricing incentives for certain services such as memberships/trading permits to attract order flow to an exchange, and later amend their fees to reflect the true value of those services, absorbing costs to provide those services in the meantime. Allowing new exchange entrants time to build and sustain market share through various pricing incentives before increasing non-transaction fees encourages market entry and promotes competition. It also enables new exchanges to mature their markets and allow market participants to trade on the new exchanges without fees serving as a potential barrier to attracting

memberships and order flow. 18 Not allowing exchanges to modify or amend such pricing incentives as their markets mature, especially when other options exchanges do not offer similar incentives, could discourage exchanges from offering such incentives if they believe the Commission would later require that exchange to continue to offer such incentives, like a nominal \$100 credit that is the subject of this proposal, and lower prices than those of its competitor exchanges. In that case, the Commission alone, and not market forces, would dictate exchange pricing.

The Exchange proposes to amend Section (3)(b) of the Fee Schedule to remove the Trading Permit Fee Credit that is denoted in footnote "*" below the Trading Permit fee table. During periods when the Trading Permit Fee Credit was in effect (the history of filings to remove the Trading Permit Fee Credit is described below), the Trading Permit Fee Credit was applicable to Members that connected via both the MEO and FIX Interfaces. Members who connected via both the MEO and FIX Interfaces were assessed the rates for both types of Trading Permits, but these Members received a \$100 monthly credit towards the Trading Permit fees applicable to the MEO Interface. The Exchange proposes to remove the Trading Permit Fee Credit and delete footnote "*" from Section (3)(b) of the Fee Schedule.

The Exchange established the Trading Permit fee credit when it first launched operations to attract order flow and increase membership by lowering the costs for Members that connect via the

³ See MIAX PEARL Successfully Launches Trading Operations, dated February 6, 2017, available at https://www.miaxoptions.com/sites/ default/files/alert-files/MIAX_Press_Release_ 02062017.pdf.

⁴ The term "Trading Permit" means a permit issued by the Exchange that confers the ability to transact on the Exchange. *See* Exchange Rule 100.

⁵ See Securities Exchange Act Release No. 80061 (February 17, 2017), 82 FR 11676 (February 24, 2017) (SR-PEARL-2017-10).

⁶ The Exchange experienced a monthly average trading volume in equity options of 3.94% for the month of March 2018. *See* Market at a Glance, available at www.miaxoptions.com (last visited November 2, 2022).

⁷ The term "MEO Interface" or "MEO" means a binary order interface for certain order types as set forth in Rule 516 into the MIAX Pearl System. See the Definitions Section of the Fee Schedule and Exchange Rule 100.

⁸ The term "FIX Interface" means the Financial Information Exchange interface for certain order types as set forth in Exchange Rule 516. See the Definitions Section of the Fee Schedule and Exchange Rule 100.

⁹ The tiers were determined by the defined term "Non-Transaction Fees Volume Based Tiers". See the Definitions Section of the Fee Schedule.

¹⁰ The term "Member" means an individual or organization that is registered with the Exchange pursuant to Chapter II of Exchange Rules for purposes of trading on the Exchange as an "Electronic Exchange Member" or "Market Maker." Members are deemed "members" under the Exchange Act. See Exchange Rule 100 and the Definitions Section of the Fee Schedule.

¹¹ See Securities Exchange Act Release No. 82867 (March 13, 2018), 83 FR 12044 (March 19, 2018) (SR-PEARL-2018-07). See the Definitions Section of the Fee Schedule for the definition of "Affiliate."

¹² See Securities Exchange Act Release No. 82867 (March 13, 2018), 83 FR 12044 (March 19, 2018) (SR-PEARL-2018-07).

means the holder of a Trading Permit who is a Member representing as agent Public Customer Orders or Non-Customer Orders on the Exchange and those non-Market Maker Members conducting proprietary trading. Electronic Exchange Members are deemed "members" under the Exchange Act. See the Definitions Section of the Fee Schedule and Exchange Rule 100.

¹⁴ The term "Market Maker" or "MM" means a Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of the Exchange Rules. See the Definitions Section of the Fee Schedule and Exchange Rule 100.

 $^{^{15}\,}See$ Securities Exchange Act Release No. 95780 (September 15, 2022), 87 FR 57732 (September 21, 2022) (SR–PEARL–2022–39).

¹⁶ See supra note 12.

¹⁷ The Exchange experienced a monthly average trading volume in equity options of 4.35% for the month of October 2022. *See* Market at a Glance, *supra* note 6 (last visited November 2, 2022).

¹⁸ See Securities Exchange Act Release No. 94894 (May 11, 2022), 87 FR 29987 (May 17, 2022) (SR-BOX-2022-17) (stating, "[t]he Exchange established this lower (when compared to other options exchanges in the industry) Participant Fee in order to encourage market participants to become Participants of BOX. . ."). See also Securities Exchange Act Release No. 90076 (October 2, 2020), 85 FR 63620 (October 8, 2020) (SR-MEMX-2020-10) ("MEMX Membership Fee Proposal") (proposing to adopt the initial fee schedule and stating that "[u]nder the initial proposed Fee Schedule, the Exchange proposes to make clear that it does not charge any fees for membership, market data products, physical connectivity or application sessions."). MEMX has seen its market share increase and recently proposed to adopt a membership fee and fees for connectivity. See Securities Exchange Act Release Nos. 93927 (January 7, 2022), 87 FR 2191 (January 13, 2022) (SR-MEMX-2021-19) (proposing to adopt membership fees); and 95299 (July 15, 2022), 87 FR 43563 (July 21, 2022) (SR-MEMX-2022-17) (proposing to adopt fees for connectivity). See also, e.g., Securities Exchange Act Release No. 88211 (February 14, 2020), 85 FR 9847 (February 20, 2020) (SR-NYSENAT-2020-05), available at https:// www.nyse.com/publicdocs/nyse/markets/nysenational/rule-filings/filings/2020/SR-NYSENat-2020-05.pdf (initiating market data fees for the NYSE National exchange after initially setting such fees at zero).

MEO Interface and FIX Interface. The Exchange believes the Trading Permit Fee Credit has achieved its purpose and the Exchange believes that it is appropriate to remove this credit in light of the current operating conditions and membership population on the Exchange.

Implementation and Procedural History

The proposed rule change will be immediately effective. The Exchange initially filed this proposal on July 1, 2021 (along with the removal of a separate credit), with the proposed changes being immediately effective. 19 In that proposal, the Exchange also proposed to increase its Trading Permit fees. Between August 2021 and September 2022, the Exchange withdrew and refiled the proposed rule change, each time to meaningfully attempt to provide additional justification for the proposed fee changes, provide enhanced details regarding the Exchange's cost methodology or to supplement its competition based arguments.20 The Commission received three comment letters from one commenter on the various filings.21 On October 25, 2022, the Exchange withdrew its latest proposal and submitted a revised proposal to only remove the Trading Permit Fee Credit (SR-PEARL-2022-45. which was not noticed by the Commission). On November 2, 2022, the Exchange withdrew SR-PEARL-2022-45 and now resubmits a revised proposal to only remove the Trading Permit Fee Credit.

2. Statutory Basis

The Exchange believes that its proposal to amend the Fee Schedule is consistent with Section 6(b) of the Act ²² in general, and furthers the objectives of

Section 6(b)(4) of the Act ²³ in particular, in that it is an equitable allocation of reasonable dues, fees and other charges among its members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act in that it is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.²⁴

The proposed changes to the Fee Schedule are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for order flow, which constrains its pricing determinations. The fact that the market for order flow is competitive has long been recognized by the courts. In NetCoalition v. Securities and Exchange Commission, the D.C. Circuit stated, "[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers' . ."25

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention to determine prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, 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." 26

The Exchange believes its proposal to remove the nominal Trading Permit Fee Credit of \$100 for EEMs that connect via both the MEO Interface and FIX Interface is reasonable, equitable and not unfairly discriminatory because all market participants will no longer be offered the ability to receive the credit.

The Exchange believes it is reasonable and equitable to remove the nominal \$100 Trading Permit Fee Credit for business and competitive reasons. The Exchange established the Trading Permit Fee Credit to lower the costs for EEMs that connect via the MEO Interface and FIX Interface as a means to attract order flow and memberships after the Exchange first launched operations. The Exchange now believes that it is appropriate to remove this credit in light of the current operating conditions and membership on the Exchange.

The Exchange commenced operations

in February 2017 27 and adopted its initial fee schedule that waived fees for Trading Permits to trade on the Exchange.²⁸ Although Trading Permit fees were waived, an initial fee structure was put in place to communicate the Exchange's intent to charge Trading Permit fees in the future. As a new exchange entrant, the Exchange chose to offer Trading Permits free of charge to encourage market participants to trade on the Exchange and experience, among things, the quality of the Exchange's technology and trading functionality. This practice is not uncommon. New exchanges often do not charge fees or charge lower fees for certain services such as memberships or trading permits to attract order flow to a new market, and later amend their fees to reflect the true value of those services, absorbing all costs to provide those services in the meantime. Allowing new exchange entrants time to build and sustain market share through various pricing incentives before increasing nontransaction fees encourages market entry and promotes competition. It also enables new exchanges to mature their markets and allow market participants to trade on the new exchanges without fees serving as a potential barrier to

Fee Credit.31

attracting memberships and order

adopted nominal fees for Trading

flow.²⁹ Later in 2018, as the Exchange's

market share increased,³⁰ the Exchange

Permits along with the Trading Permit

Continued

 $^{^{19}\,}See$ Securities Exchange Act Release No. 92366 (July 9, 2021), 86 FR 37379 (SR–PEARL–2021–32).

²⁰ See Securities Exchange Act Release Nos.
92797 (August 27, 2021), 86 FR 49399 (September 2, 2021) (SR-PEARL-2021-32) ("Suspension Order 1"); 93555 (November 10, 2021), 86 FR 64254 (November 17, 2021) (SR-PEARL-2021-54); 93895 (January 4, 2022), 87 FR 1217 (January 10, 2022) (SR-PEARL-2021-59); 94287 (February 18, 2022), 87 FR 10837 (February 25, 2022) (SR-PEARL-2022-05) ("Suspension Order 2"); 94696 (April 12, 2022), 87 FR 22987 (April 18, 2022) (SR-PEARL-2022-09); 94993 (May 26, 2022), 87 FR 33518 (June 2, 2022) (SR-PEARL-2022-23); SR-PEARL-2022-28; 95419 (August 4, 2022), 87 FR 48702 (August 10, 2022), 87 FR 57544 (September 20, 2022) (SR-PEARL-2022-35).

²¹ See Letters from Richard J. McDonald, Susquehanna International Group, LLC ("SIG"), to Vanessa Countryman, Secretary, Commission, dated September 28, 2021 and March 15, 2022, and Letter from Brian Sopinsky, General Counsel, SIG, to Vanessa Countryman, Secretary, Commission, dated May 9, 2022.

²² 15 U.S.C. 78f(b).

²³ 15 U.S.C. 78f(b)(4).

^{24 15} U.S.C. 78f(b)(5).

 ²⁵ See NetCoalition, 615 F.3d at 539 (D.C. Cir.
 2010) (quoting Securities Exchange Act Release No.
 59039 (December 2, 2008), 73 FR 74770, 74782–83
 (December 9, 2008) (SR-NYSEArca-2006-21)).

²⁶ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) ("Regulation NMS Adopting Release").

²⁷ See supra note 3.

²⁸ See supra note 5.

 $^{^{29}\,}See\,\,supra$ note 18.

³⁰ The Exchange experienced a monthly average trading volume of 3.94% for the month of March 2018. *See supra* note 6, Market at a Glance (last visited November 2, 2022).

³¹ See supra note 12. At that time, the Exchange chose to adopt a volume tier-based fee for Trading Permits along with the type of interface used—FIX or MEO—as a way to provide different choices regarding how potential Members could access the Exchange's System. This was for business and competitive reasons and to provide choice regarding Trading Permits and membership that

The Exchange recently reviewed the calculation and amount of its Trading Permit fees. In its review, the Exchange determined that the nominal Trading Permit Fee Credit of \$100 is no longer necessary to attract market share or memberships. The Exchange believes that even with the proposal to remove the nominal \$100 Trading Permit Fee Credit, the Exchange's Trading Permit fees for EEMs (\$1,000 for EEMs that connect via the FIX Interface and \$3,000 for EEMs that connect via the MEO Interface) will be similar to the rates charged by the Exchange's affiliates, Miami International Securities Exchange, LLC ("MIAX") 32 and MIAX Emerald, LLC ("MIAX Emerald"),33 and competing options exchanges in the industry for similar Trading Permits for such market participants. For example, BOX Options Exchange LLC ("BOX") 34 assesses a "Participant Fee" of \$1,500 per month; NYSE Arca, Inc. ("NYSE Arca'') 35 assesses Office and Clearing Firms Trading Permit fees of \$1,000 per month; NYSE American, LLC ("NYSE American") 36 assesses Clearing Members and Order Flow Providers "ATP Trading Permit" fees of \$1,000 per month; Nasdaq ISE LLC ("Nasdaq

had not previously existed. The Exchange has since proposed to move away from the volume tier-based Trading Permit fee structure and filed a proposal with the Commission so that its Trading Permit fee structure aligns with that of the Exchange's affiliates, MIAX and MIAX Emerald, as well as other options exchanges by assessing Market Makers Trading Permit fees based on options classes assigned. See also Securities Exchange Act Release No. 95780 (September 15, 2022), 87 FR 57732 (September 21, 2022) (SR-PEARL-2022-39) (amending the Trading Permit Fees in the MIAX Pearl Options Fee Schedule).

ISE") ³⁷ assesses Electronic Access Members "Access Fees" of \$500 per month; Cboe Exchange, Inc. ("Cboe") ³⁸ assesses Electronic Access Permit fees of \$3,000 per month and Clearing TPH Permit fees of \$2,000 per month; and Cboe C2 Exchange, Inc. ("Cboe C2") ³⁹ assesses Electronic Access Permit fees of \$1,000 per month. None of these exchanges offer a related credit.

There is no requirement, regulatory or otherwise, that any broker-dealer connect to and access any (or all of) the available options exchanges. One other exchange recently noted in a proposal to amend their own trading permit fees that of the 62 market making firms that are registered as Market Makers across Cboe, MIAX, and BOX, 42 firms access only one of the three exchanges.40 Further, the Exchange and its affiliates, MIAX and MIAX Emerald, have a total of 47 members. Of those 47 total members, 35 are members of all three exchanges, four are members of only two (2) exchanges, and eight (8) are members of only one exchange. Of those that are Market Makers today on the Exchange, two (2) are not registered as Market Makers on MIAX and one (1) is not registered as a Market Maker on MIAX Emerald. Broken down even further, of those Market Makers that use the MEO Interface and reached the Exchange's top tier for the Trading Permit fee for June 2022, one (1) Market Maker was only a Member of the

Exchange and not its two affiliates, MIAX and MIAX Emerald. The above data evidences that a Member need not be a member of all options exchanges, let alone the Exchange and its two affiliates, and market participants elect to do so based on their own business decisions and need to directly access each exchange's liquidity pool. Not only is there not an actual regulatory requirement to connect to every options exchange, the Exchange believes there is also no "de facto" or practical requirement as well, as further evidenced by the market maker membership analysis of the options exchanges discussed above. Indeed, Members choose if and how to access a particular exchange and because it is a choice, the Exchange must set reasonable pricing, otherwise prospective market makers would not connect and existing Market Makers would disconnect from the Exchange.

The Exchange believes that elasticity of demand for Exchange Membership exists when it comes to purchasing a Trading Permit and, as evidenced by the below data, prior fee proposals have resulted in Members terminating their memberships.⁴¹ For example, over the course of those prior filings, three (3) Members terminated their memberships in the time since the proposed fee increase first went into effect. In June 2021, the month immediately preceding the initial implementation of the prior proposed fee change, the Exchange had 20 users of the MEO Interface and 28 users of the FIX Interface. These numbers remained stagnant until August 2021, where one Member that utilized the MEO Interface ceased utilizing the MEO Interface and again in December 2021 where one Member that utilized the FIX Interface ceased utilizing the FIX Interface. These numbers again remained stagnant until March 2022, where another Member that utilized the FIX Interface ceased utilizing the FIX Interface. This resulted in 19 users of the MEO Interface and 26 users of the FIX Interface. Further, other exchanges have also experienced termination of memberships if their members deem permit or membership fees to be unreasonable or excessive. For example, the Exchange notes that a BOX participant modified its access to BOX in connection with the implementation of a proposed change to BOX's permit fees. 42 The absence of new memberships

³² See MIAX Fee Schedule, Section (3)(b) (assessing MIAX EEMs a flat fee of \$1,500 per month for Trading Permits).

³³ See MIAX Emerald Fee Schedule, Section (3)(b) (assessing MIAX Emerald EEMs a flat fee of \$1,500 per month for Trading Permits).

³⁴ See BOX fee schedule, Section 1, available at https://boxexchange.com/assets/BOX-Fee-Schedule-as-of-June-1-2022-1.pdf (last visited October 19, 2022). BOX's Participant Fee is the analog to the Exchange's Trading Permit fee for EEMs who use the FIX interface. BOX had an average daily market share of 6.64% for the month of October (as of October 19, 2022). See supra note 6, Market at a Glance.

³⁵ See NYSE Arca Options Fees and Charges, OTP Trading Participant Rights, p. 1, available at https://www.nyse.com/publicdocs/nyse/markets/arca-options/NYSE_Arca_Options_Fee_Schedule.pdf [last visited October 19, 2022].

³⁶ See NYSE American Options Fee Schedule, Section III, Monthly Trading Permit, Rights, Floor Access and Premium Product Fees, p. 23–24, available at https://www.nyse.com/publicdocs/nyse/markets/american-options/NYSE_American_Options_Fee_Schedule.pdf (last visited October 19, 2022). NYSE American's ATP Trading Permit fee for Clearing Members and Order Flow Providers is the analog for the Exchange's Trading Permit fee for EEMs that use the FIX interface.

³⁷ See Nasdaq ISE Options 7 Pricing Schedule, Section 8.A. Access Services, available at https:// listingcenter.nasdaq.com/rulebook/ise/rules/ ISE%20Options%207 (last visited October 19, 2022). Nasdaq ISE Options' EAM Access Fee is the analog to the Exchange's Trading Permit fee for EEMs that use the FIX Interface. Nasdaq ISE had an average daily market share of 6.35% for the month of October (as of October 19, 2022). See supra note 6, Market at a Glance.

³⁸ See Cboe Fee Schedule, Electronic Trading Permit Fees, available at https://cdn.cboe.com/resources/membership/Cboe_FeeSchedule.pdf (last visited October 19, 2022). Cboe's Electronic Access Permit fee and Clearing TPH fee are the analog to the Exchange's Trading Permit fee for EEMs that use the FIX Interface.

³⁹ See Cboe C2 Fee Schedule, Access Fees, available at https://www.cboe.com/us/options/membership/fee_schedule/ctwo/ (last visited October 19, 2022). Cboe C2's Electronic Access Permit fee is the analog to the Exchange's Trading Permit fee for EEMs that use the FIX Interface. Cboe C2 had an average daily market share of 4.65% for the month of October (as of October 19, 2022). See supra note 6, Market at a Glance.

⁴⁰ See Securities Exchange Act Release No. 94894 (May 11, 2022), 87 FR 29987 (May 17, 2022) (SR–BOX–2022–17) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Amend the Fee Schedule on the BOX Options Market LLC Facility To Adopt Electronic Market Maker Trading Permit Fees). The Exchange believes that BOX's observation demonstrates that market making firms can, and do, select which exchanges they wish to access, and, accordingly, options exchanges must take competitive considerations into account when setting fees for such access.

⁴¹ See Securities Exchange Act Release No. 95419 (August 4, 2022), 87 FR 48702 (August 10, 2022) (SR–PEARL–2022–30).

⁴² According to BOX, a Market Maker on BOX terminated its status as a Market Maker in response to BOX's proposed modification of Market Maker trading permit fees. *See* Securities Exchange Act

coupled with the termination of two memberships on the Exchange, as well as similar membership changes on another options exchange in relation to a trading permit fee increase, clearly shows that elasticity of demand exists.

The Exchange notes that there are material costs associated with providing the infrastructure and headcount to fully-support access to the Exchange. The Exchange incurs technology expenses related to establishing and maintaining Information Security services, enhanced network monitoring and customer reporting associated with its network technology. While some of the expense is fixed, much of the expense is not fixed, and thus increases as the expenses associated with access services for Members increases. For example, new Members to the Exchange may require the purchase of additional hardware to support those Members as well as enhanced monitoring and reporting of customer performance that the Exchange provides. Further, as the total number of Members increase, the Exchange may need to increase its data center footprint and consume more power, resulting in increased costs charged by their third-party data center provider. Accordingly, the cost to the Exchange to provide access to its Members is not fixed. The Exchange believes the proposal to remove the Trading Permit Fee Credit is reasonable in order to offset a portion of the costs to the Exchange associated with providing access to its quote and order infrastructure.

The Exchange again notes that it operates in a highly competitive market in which market makers can readily favor competing venues if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees for services and products, in addition to order flow, to remain competitive with other exchanges. The Exchange believes that the proposed changes reflect this competitive environment. The Exchange again notes it is not aware of any reason why Members could not simply drop their access to an exchange (or not initially access an exchange) if an exchange were to establish prices for its nontransaction fees that, in the determination of such market

Release No. 94894 (May 11, 2022), 87 FR 29987 (May 17, 2022) (SR–BOX–2022–17). BOX noted, and the Exchange agrees, that this Market Maker's decision demonstrates that Market Makers can, and do, alter their membership status if they deem permit fees at an exchange to be unsuitable for their business needs, thus demonstrating the competitive environment for Market Maker permit fees and the constraints on options exchanges when setting Market Maker permit fees.

participant, did not make business or economic sense to access such exchange. The Exchange again notes that no broker-dealer is required by rule, regulation, or competitive forces to be a Member on the Exchange.

Accordingly, the Exchange believes removal of the nominal \$100 Trading Permit Fee Credit is reasonable and equitable. It is also not unfairly discriminatory as the removal of the credit applies equally to all EEMs and the Exchange's Trading Permit fees for EEMs are in line with similar fees charged by competitor exchanges.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,⁴³ the Exchange believes that the proposed rule change would not impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange believes the removal of the Trading Permit fee credit will not place certain market participants at a relative disadvantage to other market participants because, in order to attract order flow when the Exchange first launched operations, the Exchange established this credit to lower the initial fixed cost for Members. The Exchange now believes that it is appropriate to remove this credit in light of the current operating conditions, including the Exchange's overall membership and the current type and amount of volume executed on the Exchange. The Exchange believes that the Exchange's current rebates and fees will still allow the Exchange to remain highly competitive such that the Exchange should continue to attract order flow and maintain market share. The proposed fee change will not impact intra-market competition because it will apply to all Members equally.

Inter-Market Competition

The Exchange operates in a highly competitive market in which market participants can readily favor one of the 15 competing options venues if they deem fee levels at a particular venue to be excessive. Based on publicly-available information, and excluding index-based options, no single exchange has more than approximately 16% market share. Therefore, no exchange possesses significant pricing power regarding memberships or in the execution of multiply-listed equity and

exchange-traded fund ("ETF") options order flow. Over the course of 2021 and 2022, the Exchange's market share has fluctuated between approximately 3-6% of the U.S. equity options industry.44 The Exchange is not aware of any evidence that a market share of approximately 3–6% provides the Exchange with anti-competitive pricing power when it comes to competition for memberships. The Exchange believes that the ever-shifting market share among exchanges from month to month demonstrates that market participants can discontinue memberships in response to fee changes. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract and retain memberships on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange responded to comment letters in a prior proposal.⁴⁵

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,46 and Rule 19b-4(f)(2) 47 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 shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

• Use the Commission's internet comment form (http://www.sec.gov/rules/sro.shtml); or

^{43 15} U.S.C. 78f(8).

⁴⁴ See supra note 6.

⁴⁵ See supra note 20.

⁴⁶ 15 U.S.C. 78s(b)(3)(A)(ii).

⁴⁷ 17 CFR 240.19b-4(f)(2).

• Send an email to *rule-comments@* sec.gov. Please include File Number SR–PEARL–2022–47 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-PEARL-2022-47. 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-PEARL-2022-47 and should be submitted on or before December 5, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴⁸

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–24650 Filed 11–10–22; 8:45 am]

BILLING CODE 8011-01-P

[Public Notice: 11902]

Determination Under Section 614(a)(1) of the Foreign Assistance Act of 1961 for Assistance in Response to the Global COVID-19 Pandemic

Pursuant to the authority vested in me by section 614(a)(1) of the Foreign Assistance Act of 1961 (FAA), the President's Memorandum of Delegation, dated August 26, 2022, and Department of State Delegation of Authority 513, I hereby determine that it is important to the security interests of the United States to use up to \$215 million from the Economic Support Fund under title IX of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2021 (Div. K, Pub. L. 116–260) to furnish assistance in response to the global COVID-19 pandemic, without regard to any provision of law within purview of section 614(a)(1) of the FAA.

This determination shall be reported to Congress and published in the **Federal Register**.

Dated: September 1, 2022.

Brian P. McKeon,

Deputy Secretary of State for Management and Resources, Department of State.

[FR Doc. 2022–24638 Filed 11–10–22; 8:45 am]

BILLING CODE 4710-10-P

DEPARTMENT OF STATE

[Public Notice 11917]

60-Day Notice of Proposed Information Collection: Medical History and Examination

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to January 13, 2023.

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

• Web: Persons with access to the internet may comment on this notice by going to www.Regulations.gov. You can search for the document by entering

- "Docket Number: DOS-2022-0045" in the Search field. Then click the "Comment Now" button and complete the comment form.
 - Email: Yellandmj@state.gov.
- Regular Mail: Send written comments to: Medical Director, Office of Medical Clearances, Bureau of Medical Services, 2401 E Street NW, SA-1, Room L-101, Washington, DC 20522-0101.
- *Fax:* 202–647–0292, Attention: Medical Clearance Director.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT:

Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument, and supporting documents, should be sent to Michelle Yelland, Director of Medical Clearances at 202–663–1657 or Yellandmj@state.gov.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Medical History and Examination.
 - OMB Control Number: 1405-0068.
- *Type of Request:* Revision of a Currently Approved Collection.
- Originating Office: Bureau of Medical Services—Medical Clearances Department.
- Form Numbers: DS-1843 and DS-1622.
- *Respondents:* Contractors and eligible family members.
- Estimated Number of Respondents: 2,039.
- Estimated Number of Responses: 2,039.
 - Average Time per Response: 1 hour.
- Total Estimated Burden Time: 2,039 hours.
- Frequency: Upon application for an overseas position and then intermittent, as needed.
- *Obligation to Respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

DEPARTMENT OF STATE

^{48 17} CFR 200.30-3(a)(12).

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

Forms DS-1843 and DS-1622 collect medical history, screenings and physical examinations for all individuals applying for overseas positions, including their eligible family members. Forms DS-1843 and DS-1622 are designed to collect sufficient and current medical information on the individual for a medical provider to make a medical clearance determination for initial appointment to an overseas assignment. They are also used to determine whether the individual or eligible family member will have appropriate medical and/or educational resources at a diplomatic mission/host country abroad to maintain the health and safety of the individual or family member. The forms were updated to include questions regarding employment agency information for non-foreign service agencies.

Methodology

The respondent will obtain the DS–1843 and DS1622 forms from their human resources representative or download the forms from a department website. The respondent will complete and submit the forms offline.

Michelle Yelland,

Director of Medical Clearances, Bureau of Medical Clearances, Department of State. [FR Doc. 2022–24665 Filed 11–10–22; 8:45 am]

BILLING CODE 4710-36-P

SUSQUEHANNA RIVER BASIN COMMISSION

Grandfathering (GF) Registration Notice

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists Grandfathering Registration for projects by the Susquehanna River Basin Commission during the period set forth in **DATES.**

DATES: October 1–31, 2022.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary to the Commission, telephone:

(717) 238–0423, ext. 1312; fax: (717) 238–2436; email: *joyler@srbc.net*. Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists GF Registration for projects, described below, pursuant to 18 CFR part 806, subpart E, for the time period specified above:

1. Hickory Heights, Inc.—Hickory Heights Golf Club, GF Certificate No. GF–202210226, North Codorus Township, York County, Pa.; Well 1; Issue Date: October 26, 2022.

2. Kline Township Municipal Authority—Public Water Supply System, GF Certificate No. GF– 202210227, Kline Township, Schuylkill County, Pa.; combined withdrawal from Well 1, Well 2, Well 8, Honey Brook Reservoir, and No. 8 Reservoir; Issue Date: October 26, 2022.

3. Pennsy Supply, Inc.—Pittston Quarry, GF Certificate No. GF– 202210228, Jenkins Township, Luzerne County, Pa.; Well 1; Issue Date: October 26, 2022.

4. Wellsboro Borough Municipal Authority—Public Water Supply System, GF Certificate No. GF– 202210229, Duncan and Charleston Townships, Tioga County, Pa.; see Addendum; Issue Date: October 26, 2022.

5. Emporium Country Club, Inc.— Emporium Country Club, GF Certificate No. GF–202210230, Lumber Township, Cameron County, Pa.; Driftwood Branch Sinnemahoning Creek, spring-fed ponds, and consumptive use; Issue Date: October 26, 2022.

6. Village of Horseheads—Public Water Supply System, GF Certificate No. GF–202210231, Town of Horseheads, Chemung County, N.Y.; Wells 1, 2, and 4; Issue Date: October 26, 2022.

Authority: Public Law 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806 and 808.

Dated: November 8, 2022.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2022-24694 Filed 11-10-22; 8:45 am]

BILLING CODE 7040-01-P

SUSQUEHANNA RIVER BASIN COMMISSION

Commission Meeting

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: The Susquehanna River Basin Commission will conduct its regular business meeting on December 15, 2022

in Harrisburg, Pennsylvania. Details concerning the matters to be addressed at the business meeting are contained in the SUPPLEMENTARY INFORMATION section of this notice. Also the Commission published a document in the Federal Register on October 13, 2022, concerning its public hearing on November 3, 2022, in Harrisburg, Pennsylvania.

DATES: The meeting will be held on Thursday, December 15, 2022, at 9 a.m. **ADDRESSES:** This public meeting will be conducted in person and digitally from the Susquehanna River Basin Commission, 4423 N Front Street, Harrisburg, Pennsylvania 17110.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary to the Commission, telephone: 717–238–0423; fax: 717–238–2436.

SUPPLEMENTARY INFORMATION: The business meeting will include actions or presentations on the following items: (1) adoption of the regulatory program fee schedule for CY2023; (2) adoption of a resolution recognizing the 50th anniversary of the Clean Water Act; (3) approval of contracts, grants and agreements; (4) and actions on 13 regulatory program projects.

This agenda is complete at the time of issuance, but other items may be added, and some stricken without further notice. The listing of an item on the agenda does not necessarily mean that the Commission will take final action on it at this meeting. When the Commission does take final action, notice of these actions will be published in the Federal Register after the meeting. Any actions specific to projects will also be provided in writing directly to project sponsors.

The meeting will be conducted both in person at the Susquehanna River **Basin Commission Harrisburg** headquarters and digitally. The public is invited to attend the Commission's business meeting. You can access the Business Meeting through a computer (Audio and Video) by following the link: https://srbc.webex.com/srbc/j.php? MTID=meb4986cc5831b88ea 7d5b1ef5151e7b6 then enter meeting number 177 203 4471 and password CommBusMtg1215. You may also participant telephonically by dialing 1-877-668-4493 and entering the meeting number 177 203 4471 followed by the

Written comments pertaining to items on the agenda at the business meeting may be mailed to the Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, Pennsylvania 17110–1788, or submitted electronically through www.srbc.net/about/meetings-

events/business-meeting.html. Such comments are due to the Commission on or before November 14, 2022. Comments will not be accepted at the business meeting noticed herein.

Authority: Public Law 91–575, 84 Stat. 1509 *et seq.*, 18 CFR parts 806, 807, and 808.

Dated: November 8, 2022.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2022–24691 Filed 11–10–22; 8:45 am] **BILLING CODE P**

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Approved for Consumptive Uses of Water

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists Approvals by Rule for projects by the Susquehanna River Basin Commission during the period set forth in **DATES.**

DATES: October 1–31, 2022.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT:

Jason E. Oyler, General Counsel and Secretary to the Commission, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: joyler@srbc.net. Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists the projects, described below, receiving approval for the consumptive use of water pursuant to the Commission's approval by rule process set forth in 18 CFR 806.22 (f) for the time period specified above:

Water Source Approval—Issued Under 18 CFR 806.22 (f)

1. Chesapeake Appalachia, L.L.C.; Pad ID: McCabe; ABR–201008157.R2; Towanda Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: October 17, 2022.

2. Chesapeake Appalachia, L.L.C.; Pad ID: Rylee; ABR–20100610.R2; Auburn Township, Susquehanna County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: October 17, 2022.

3. Chesapeake Appalachia, L.L.C.; Pad ID: Thall; ABR–201008140.R2; Albany Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: October 17, 2022.

4. Chesapeake Appalachia, L.L.C.; Pad ID: Wolf; ABR–201008158.R2; Athens

Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: October 17, 2022.

5. EQT ARO LLC; Pad ID: Clearview HC Pad A; ABR–201007076.R2; Gamble Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 17, 2022.

6. EQT ARO LLC; Pad ID: COP Tr 285 Pad E; ABR–201007074.R2; Grugan Township, Clinton County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 17, 2022.

7. EQT ARO LLC; Pad ID: Frank L Hartley Pad A; ABR–201008144.R2; Cogan House Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 17,

8. PPG Operations LLC; Pad ID: COP 324–A; ABR–202210002; Girard Township, Clearfield County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: October 17, 2022.

9. Repsol Oil & Gas USA, LLC; Pad ID: CALABRO T2; ABR-201505007.R1; Orange Town, Schuyler County, NY; Consumptive Use of Up to 0.0800 mgd; Approval Date: October 17, 2022.

10. Repsol Oil & Gas USA, LLC; Pad ID: FROST 2; ABR–201505005.R1; Orange Town, Schuyler County, NY; Consumptive Use of Up to 0.0800 mgd; Approval Date: October 17, 2022.

11. Seneca Resources Company, LLC; Pad ID: B09–S; ABR–202210001; Shippen Township, Cameron County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 17, 2022.

12. Seneca Resources Company, LLC; Pad ID: Kinnan 845; ABR– 201008135.R2; Middlebury Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 17, 2022.

13. BKV Operating, LLC; Pad ID: P&G Warehouse 1–1H; ABR–201008156.R2; Meshoppen Township, Wyoming County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: October 19, 2022.

14. BKV Operating, LLC; Pad ID: Ricci Well Pad; ABR–201208019.R2; Bridgewater Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: October 19, 2022.

15. Chesapeake Appalachia, L.L.C.; Pad ID: SGL-12 L SOUTH UNIT PAD; ABR-202010001.1; Leroy Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: October 19, 2022.

16. Coterra Energy Inc.; Pad ID: SalanskyT P1; ABR-201208022.R2; Gibson Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: October 19, 2022. 17. Range Resources—Appalachia, LLC; Pad ID: McWilliams Unit #6H— #10H Well Pad; ABR—201208015.R2; Cogan House Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 19,

18. Range Resources—Appalachia, LLC; Pad ID: Null Bobst Unit 1H–5H; ABR–201208018.R2; Cogan House Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 19, 2022.

19. Repsol Oil & Gas USA, LLC; Pad ID: GREEN NEWLAND LLC (05 067); ABR–201008151.R2; Warren Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: October 19, 2022.

20. Repsol Oil & Gas USA, LLC; Pad ID: KUHLMAN (05 258) M; ABR—201208023.R2; Windham Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: October 19,2022.

21. Seneca Resources Company, LLC; Pad ID: DCNR Tract 001 1H; ABR– 201008142.R2; Sweden Township, Potter County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 19, 2022.

22. Chesapeake Appalachia, L.L.C.; Pad ID: SGL 289B; ABR–201009009.R2; West Burlington Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: October 24, 2022.

23. Chesapeake Appalachia, L.L.C.; Pad ID: Stoudt; ABR–201009011.R2; Overton Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: Ocobert 24, 2022.

24. Chesapeake Appalachia, L.L.C.; Pad ID: Tague East Drilling Pad; ABR– 201208024.R2; Lemon Township, Wyoming County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: October 24, 2022.

25. Chesapeake Appalachia, L.L.C.; Pad ID: Vera; ABR–201009001.R2; Fox Township, Sullivan County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: October 24, 2022.

26. EQT ARO LLC; Pad ID: Plants Evergreen Farm Pad A; ABR— 201009003.R2; Cascade Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 24, 2022.

27. Repsol Oil & Gas USA, LLC; Pad ID: RITZ (03 073) G; ABR–201009019.R2; Columbia Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: October 24, 2022.

28. Chesapeake Appalachia, L.L.C.; Pad ID: Atgas; ABR–201008066.R2; Leroy Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: October 30, 2022.

- 29. Chesapeake Appalachia, L.L.C.; Pad ID: Bluegrass; ABR–201007103.R2; Rush Township, Susquehanna County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: October 30, 2022.
- 30. Repsol Oil & Gas USA, LLC; Pad ID: ANTISDEL (05 035) M; ABR—201009015.R2; Warren and Windham Townships, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: October 30, 2022.
- 31. Repsol Oil & Gas USA, LLC; Pad ID: UGLIUZZA (05 006) L; ABR—201007086.R2; Pike Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: October 30, 2022
- 32. Repsol Oil & Gas USA, LLC; Pad ID: WRAY (03 058) M; ABR—20100649.R2; Wells Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: October 30, 2022.
- 33. Chesapeake Appalachia, L.L.C.; Pad ID: Williams; ABR–201009031.R2; Ulster Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: October 31, 2022.
- 34. Inflection Energy (PA) LLC; Pad ID: Smith West Well Site; ABR–202210004; Gamble Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 31, 2022.
- 35. PPG Operations LLC; Pad ID: COP 324 Elk; ABR–202210003; Girard Township, Clearfield County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: October 31, 2022.
- 36. Seneca Resources Company, LLC; Pad ID: COP Pad J; ABR–201009022.R2; Lawrence Township, Clearfield County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 31, 2022.
- 37. Seneca Resources Company, LLC; Pad ID: PHC Pad T; ABR–201009039.R2; Lawrence Township, Clearfield County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 31, 2022.
- 38. Seneca Resources Company, LLC; Pad ID: Wood 496; ABR–201009026.R2; Richmond Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: October 31, 2022.

Authority: Public Law 91–575, 84 Stat. 1509 et seq., 18 CFR parts 806 and 808.

Dated: November 8, 2022.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2022–24695 Filed 11–10–22; 8:45 am]

BILLING CODE 7040-01-P

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Approved for Minor Modifications

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists the minor modifications approved for a previously approved project by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: October 1–31, 2022.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT:

Jason E. Oyler, General Counsel and Secretary to the Commission, telephone: (717) 238–0423, ext. 1312; fax (717) 238–2436; email: joyler@srbc.net. Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists previously approved projects, receiving approval of minor modifications, described below, pursuant to 18 CFR 806.18 or to Commission Resolution Nos. 2013–11 and 2015–06 for the time period specified above.

- 1. Seneca Resources Company, LLC (Cowanesque River), Docket No. 20220920, Deerfield Township, Tioga County, Pa.; approval to change intake design and location; Approval Date: October 18, 2022.
- 2. Clearfield Municipal Authority (Moose Creek Well 3), Docket No. 20220921, Lawrence Township, Clearfield County, Pa.; approval to change monitoring requirements; Approval Date: October 26, 2022.
- 3. East Cocalico Township Authority (Well M), Docket No. 20220606, West Cocalico Township, Lancaster County, Pa.; correction to Special Condition 23; Correction Issue Date: October 31, 2022.

Authority: Public Law 91–575, 84 Stat. 1509 *et seq.*, 18 CFR parts 806 and 808.

Dated: November 8, 2022.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2022–24692 Filed 11–10–22; 8:45 am]

BILLING CODE 7040-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Extension to Public Comment Period—Notice of Intent To Prepare an Environmental Impact Statement, Initiate Section 106 Consultation, and Request for Scoping Comments for the Proposed Airfield, Safety, and Terminal Improvement Project at West Virginia International Yeager Airport, Charleston, Kanawha County, West Virginia

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

ACTION: Notice of a 12-day extension to the public scoping comment period for the proposed Airfield, Safety, and Terminal Improvement Project at West Virginia International Yeager Airport, Charleston, Kanawha County, West Virginia.

SUMMARY: The Federal Aviation Administration (FAA) is issuing this notice to advise the public that the scoping comment period for the proposed Airfield, Safety, and Terminal Improvement Project and its connected actions (Proposed Action) has been extended by 12 days. This notice announces the extension of the public comment period to solicit public comments on the scope of the environmental impact statement (EIS).

DATES: The EIS scoping comment period began on September 30, 2022, was originally scheduled to end on November 17, 2022, and has been extended to end on November 29, 2022. All comments must be received by no later than 5 p.m. Eastern Time, Tuesday, November 29, 2022.

FOR FURTHER INFORMATION CONTACT: Mr. Andrew Brooks, Environmental Program Manager, Eastern Regional Office, AEA–610, Federal Aviation Administration, 1 Aviation Plaza, Jamaica, NY 11434. Telephone: 718–553–2511.

SUPPLEMENTARY INFORMATION: The purpose of the scoping process is to receive input from the public, as well as from federal, state, and local agencies that have legal jurisdiction and/or special expertise, with respect to any potential environmental impacts associated with the Proposed Action, as well as concerns, issues, and alternatives they believe should be addressed in the EIS. During the scoping process, questions regarding the scope and EIS process will be considered. More information about the Proposed Action, the EIS process, and the scoping meetings can be found at www.yeagerairporteis.com.

The scoping process for this EIS includes a comment period for interested agencies and members of the public to submit comments with respect to any potential environmental impacts associated with the Proposed Action, or comments representing the concerns, issues, and alternatives they believe should be addressed in the EIS.

During the ongoing scoping comment period, the FAA received several requests from members of the public for an extension to the comment period. In response, the FAA has agreed to extend the scoping comment period by 12 additional days. The public comment period on the scoping phase of the EIS will now end at 5 p.m. eastern time on November 29, 2022. Comments should be addressed to the individual listed in FOR FURTHER INFORMATION CONTACT, or by email to comments@ yeagerairporteis.com.

Issued in Beaver, West Virginia, November 7, 2022.

Matthew Digiulian,

Manager, Beckley Airport Field Office, Airports Division, Eastern Region.

[FR Doc. 2022–24659 Filed 11–10–22; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA-2022-0002-N-17]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, FRA will seek approval of the Information Collection Request (ICR) abstracted below. Before submitting this ICR to the Office of Management and Budget (OMB) for approval, FRA is soliciting public comment on specific aspects of the activities identified in the ICR.

DATES: Interested persons are invited to submit comments on or before January 13, 2023.

ADDRESSES: Written comments and recommendations for the proposed ICR should be submitted on *regulations.gov* to the docket, Docket No. FRA-2022-0002-N-14. All comments received will be posted without change to the docket, including any personal information provided. Please refer to the assigned

OMB control number in any correspondence submitted. FRA will summarize comments received in response to this notice in a subsequent notice and include them in its information collection submission to OMB for approval.

FOR FURTHER INFORMATION CONTACT: Ms. Hodan Wells, Information Collection Clearance Officer, at email: Hodan.Wells@dot.gov or telephone: (202) 868–9412, or Ms. Senya Waas, Attorney Adviser, at email: Senyaann.Waas@dot.gov or telephone: (202) 875–4158.

SUPPLEMENTARY INFORMATION: The PRA. 44 U.S.C. 3501-3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to provide 60-days' notice to the public to allow comment on information collection activities before seeking OMB approval of the activities. See 44 U.S.C. 3506, 3507; 5 CFR 1320.8–1320.12. Specifically, FRA invites interested parties to comment on the following ICR regarding: (1) whether the information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways for FRA to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology. See 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1).

FRA believes that soliciting public comment may reduce the administrative and paperwork burdens associated with the collection of information that Federal statutes and regulations mandate. In summary, FRA reasons that comments received will advance three objectives: (1) reduce reporting burdens; (2) organize information collection requirements in a "user-friendly" format to improve the use of such information; and (3) accurately assess the resources expended to retrieve and produce information requested. See 44 U.S.C. 3501

The summary below describes the ICR that FRA will submit for OMB clearance as the PRA requires:

Title: Positive Train Control (PTC) and Other Signal Systems.

OMB Control Number: 2130–0553. Abstract: FRA's regulations require that both railroads and PTC vendors and

suppliers notify FRA of certain PTC system errors and malfunctions. 49 CFR 236.1023. For example, railroads must maintain a database of all safetyrelevant hazards identified in their PTC Safety Plans (PTCSP) and those that had not previously been identified in their PTCSPs. 49 CFR 236.1023(e). If the frequency of a safety-relevant hazard exceeds the thresholds in a railroad's PTCSP, or such hazard has not been previously identified in a railroad's risk analysis, then the railroad must notify FRA of the failure, malfunction, or defective condition that decreased or eliminated the safety functionality of the railroad's PTC system. 49 CFR 236.1023(e)(1). In addition, FRA's regulations require PTC vendors and suppliers to notify FRA of any safetyrelevant failure, defective condition, or previously unidentified hazard discovered by the vendor or supplier and the identify of each affected and notified railroad. 49 CFR 236.1023(h)(2). Currently, each railroad or PTC vendor and supplier that must submit notifications of such a failure, malfunction, or defective condition does so by emailing the information to an FRA inbox

(FRAPart2361023Notification@dot.gov). The information is sent in different formats by each railroad or PTC supplier and vendor because there is currently no standardized form.

Therefore, FRA is hereby proposing to standardize the reporting process required by 49 CFR 236.1023(e)(1), (h), and (f) by creating the Errors and Malfunctions Notification Form (Form FRA F 6180.179), which is one part of the existing information collection request under OMB Control No. 2130-0553. This proposed Form FRA F 6180.179 will be in an Excel format and will make it easier for the entities to notify FRA of each applicable failure, malfunction, or defective condition, and for FRA to synthesize and act on the reported failure. The Errors and Malfunctions Notification Form would not change the requirements that each railroad or PTC supplier and vendor currently must follow to notify FRA of each reportable failure, malfunction, or defective condition. See, e.g., 49 CFR 236.1023(e), (h), and (f). The proposed Form FRA F 6180.179 would be submitted to

FRAPart2361023Notification@dot.gov within the 15-day deadline under 49 CFR 236.1023(f)(1).

With the current reporting process, FRA estimated that each notification would take 8 hours to prepare. With the new standardized Form, FRA estimates that, on average, each notification will reduce to 7.5 hours to prepare if the

railroad or PTC supplier or vendor uses the FRA-provided Excel Form. This estimate is based on the fact that the proposed new Form FRA F 6180.179 offers drop-down menus that would allow railroads or PTC suppliers and vendors to select an answer from an established list, instead of creating each answer from scratch. The revised burden would also account for the review of the instructions in the FRAprovided Excel Form. Thus, FRA estimates that by creating this Form, the total annual burden hours will decrease by 14 hours.¹

Type of Request: Revision to a currently approved collection.

Affected Public: Businesses.
Form(s): FRA F 6180.152 (existing form) and FRA F 6180.179 (new form).
Respondent Universe: 742 railroads.
Frequency of Submission: On occasion.

Reporting Burden:

CFR section Respondent universe Total annual responses Average time per response Total annual burden hours	Total annual dollar cost equivalent	Total annual burden hours		Total annual responses	Respondent universe	CFR section
(A) (B) (C) = A * B	(D) = C * wage rates 2	(C) = A * B	(B)	(A)		
	\$3,850	50	5 hours		42 railroads	235.6(c)—Expedited application for approval of certain changes described in this section.
	385	5				—Copy of expedited application to labor union
on of certain signal system changes.		6	6 hours		42 railroads	 Railroad letter rescinding its request for expedited application of certain signal system changes.
	385	5	5 hours	1 application	42 railroads	 Revised application for certain signal system changes.
		0.5				—Copy of railroad revised application to labor union
automatic signal locations, and controlled	481	6.25	15 minutes	25 plan changes	700 railroads	236.1—Railroad-maintained signal plans at all interlockings, automatic signal locations, and controlled points, and updates to ensure accuracy.
in control, cab signal, and PTC territory in	385	5	30 minutes	10 timetable instructions	700 railroads	236.15—Designation of automatic block, traffic control, train stop, train control, cab signal, and PTC territory in timetable instructions.
	24,640	320	160 hours	2 plans	2 railroads	236.18—Software management control plan—New railroads.
signals shall be defined in the carrier's le Book or Special Instructions. Modification like the book of Special Instructions. Modification like the book of Special Instructions after such like the book of Special Instructions. Modification like the book of Special Instruction is such as the book of Special Instruction is su	154	2	1 hour	2 modifications	700 railroads	236.23(e)—The names, indications, and aspects of road-way and cab signals shall be defined in the carrier's Operating Rule Book or Special Instructions. Modifications shall be filed with FRA within 30 days after such modifications become effective.
	487,934	6,336.81	5 seconds		742 railroads	236.587(d)—Certification and departure test results
ilroad Safety Program Plan (RSPP)—New 2 railroads	6,160	80	40 hours	2 RSPPs	2 railroads	236.905(a)—Railroad Safety Program Plan (RSPP)—New railroads.
ng and approval of a joint Product Safety 742 railroads	240,000	2,000	2,000 hours	1 joint plan	742 railroads	236.913(a)—Filing and approval of a joint Product Safety Plan (PSP).
ional filing/petition for special approval 742 railroads	1,925	25	50 hours		742 railroads	(c)(1)—Informational filing/petition for special approval
	96	1.25	5 hours		742 railroads	(c)(2)—Response to FRA's request for further data after informational filing.
days after receipt of the Notice of Product ments.	19	0.25	1 hour		742 railroads	(d)(1)(ii)—Response to FRA's request for further informa- tion within 15 days after receipt of the Notice of Product Development (NOPD).
and planned development of the product. tions.	96	1.25	5 hours		742 railroads	(d)(1)(iii)—Technical consultation by FRA with the railroad on the design and planned development of the product.
	19	0.25	1 hour		742 railroads	(d)(1)(v)—Railroad petition to FRA for final approval of NOPD.
ated with a petition for approval of PSP or	3,850	50	50 hours	1 request	742 railroads	(d)(2)(ii)—Response to FRA's request for additional infor- mation associated with a petition for approval of PSP or PSP amendment.
to FRA on railroad informational filing or 742 railroads	385	5	10 hours	0.5 comments/letters	742 railroads	(e)—Comments to FRA on railroad informational filing or special approval petition.
	3,080	40	20 hours	2 amendments	742 railroads	(h)(3)(i)—Railroad amendment to PSP
	7,700	100				(j)—Railroad field testing/information filing document
ns specified in the PSP.		2,080				236.917(a)—Railroad retention of records: results of tests and inspections specified in the PSP.
	3,080	40	40 hours	1 report	13 railroads	(b)—Railroad report that frequency of safety-relevant haz- ards exceeds threshold set forth in PSP.
countermeasures taken to reduce the fre-	770	10	10 hours	1 report	13 railroads	(b)(3)—Railroad final report to FRA on the results of the analysis and countermeasures taken to reduce the fre- quency of safety-relevant hazards.
	3,080	40	40 hours	1 OMM update	13 railroads	236.919(a)—Railroad Operations and Maintenance Man- ual (OMM).
	3,080	40	40 hours	1 plan update	13 railroads	(b)—Plans for proper maintenance, repair, inspection, and testing of safety-critical products.
	3,080	40	40 hours	1 revision	13 railroads	(c)—Documented hardware, software, and firmware revisions in OMM.
	1	40	40 hours	1 program	13 railroads	236.921 and 236.923(a)—Railroad Training and Qualifica-
l. 6.923(a)—Railroad Training and Qualifica-	3,080	40				tion Program.

 $^{^{1}}$ The current inventory exhibits a total burden of 51,993 hours and 4,567,826 responses, while the

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual dollar cost equivalent	
		(A)	(B)	(C) = A * B	(D) = C * wage rates ²	
236.1001(b)—A railroad's additional or more stringent rules than prescribed under 49 CFR part 236, subpart I.	38 railroads	1 rule or instruction	40 hours	40	4,800	
236.1005(b)(4)(i)-(ii)—A railroad's submission of estimated traffic projections for the next 5 years, to support a request, in a PTC Implementation Plan (PTCIP) or a request for amendment (RFA), not to implement a PTC system based on reductions in rail traffic.						
(b)(4)(iii)—A railroad's request for a <i>de minimis</i> exception, in a PTCIP or an RFA, based on a minimal quantity of poisonous-by-inhalation materials traffic.	7 Class I railroads	1 exception request	40 hours	40	3,080	
(b)(5)—A railroad's request to remove a line from its PTCIP based on the sale of the line to another railroad and any related request for FRA review from the acquir- ing railroad.	The burden is accounted for under 49 CFR 236.1009(a) and 236.1021.					
(g)(1)(i)—A railroad's request to temporarily reroute trains not equipped with a PTC system onto PTC-equipped tracks and vice versa during certain emergencies.	38 railroads	45 rerouting extension requests.	8 hours	360	27,720	
(g)(1)(ii)—A railroad's written or telephonic notice of the conditions necessitating emergency rerouting and other required information under 236.1005(i).	38 railroads	45 written or telephonic notices.	2 hours	90	6,930	
(g)(2)—A railroad's temporary rerouting request due to planned maintenance not exceeding 30 days.	38 railroads	720 requests	8 hours	5,760	443,520	
(h)(1)—A response to any request for additional informa- tion from FRA, prior to commencing rerouting due to	38 railroads	10 requests	2 hours	20	1,540	
planned maintenance. (h)(2)—A railroad's request to temporarily reroute trains due to planned maintenance exceeding 30 days.	38 railroads	160 requests	8 hours	1,280	98,560	
236.1006(b)(4)(iii)(B)—A progress report due by December 31, 2020, and by December 31, 2022, from any Class II or III railroad utilizing a temporary exception under this section.	262 railroads	5 reports	16 hours	80	6,160	
(b)(5)(vii)—A railroad's request to utilize different yard movement procedures, as part of a freight yard movements exception.						
236.1007(b)(1)—For any high-speed service over 90 miles per hour (mph), a railroad's PTC Safety Plan (PTCSP) must additionally establish that the PTC system was designed and will be operated to meet the failsafe operation criteria in appendix C.	The burden is accounted for under 49 CFR 236.1015 and 236.1021.					
(c)—An HSR-125 document accompanying a host railroad's PTCSP, for operations over 125 mph.	38 railroads	1 HSR-125 document	3,200 hours	3,200	384,000	
(c)(1)—A railroad's request for approval to use foreign service data, prior to submission of a PTCSP.	38 railroads	0.33 requests	8,000 hours	2,640	203,280	
(d)—A railroad's request in a PTCSP that FRA excuse compliance with one or more of this section's require-	38 railroads	1 request	1,000 hours	1,000	120,000	
ments. 236.1009(a)(2)—A PTCIP if a railroad becomes a host railroad of a main line requiring the implementation of a PTC system, including the information under 49 U.S.C. 20157(a)(2) and 49 CFR 236.1011.	264 railroads	1 PTCIP	535 hours	535	64,200	
(a)(3)—Any new PTCIPs jointly filed by a host railroad and a tenant railroad.	264 railroads	1 joint PTCIP	267 hours	267	32,040	
(b)(1)—A host railroad's submission, individually or jointly with a tenant railroad or PTC system supplier, of an un-	264 railroads	1 document	8 hours	8	616	
modified Type Approval. (b)(2)—A host railroad's submission of a PTC Development Plan (PTCDP) with the information required under 49 CFR 236.1013, requesting a Type Approval for a PTC system that either does not have a Type Approval or has a Type Approval that requires one or more variances.	264 railroads	1 PTCDP	2,000 hours	2,000	154,000	
(d)—A host railroad's submission of a PTCSP	. The burdens are accounted for under 49 CFR 236.1015.					
(e)(3)—Any request for full or partial confidentiality of a PTCIP, Notice of Product Intent (NPI), PTCDP, or PTCSP.	38 railroads	10 confidentiality requests.	8 hours	80	6,160	

CFR section	Respondent universe	Total annual responses	Average time per	Total annual	Total annual dollar cost	
of a section	nespondent universe	·	response	burden hours	equivalent	
		(A)	(B)	(C) = A * B	(D) = C * wage rates ²	
(h)—Any responses or documents submitted in connection with FRA's use of its authority to monitor, test, and inspect processes, procedures, facilities, documents, records, design and testing materials, artifacts, training materials and programs, and any other information used in the design, development, manufacture, test, implementation, and operation of the PTC system, including interviews with railroad personnel.	38 railroads	36 interviews and documents.	4 hours	144	11,088	
(j)(2)(iii)—Any additional information provided in response to FRA's consultations or inquiries about a PTCDP or PTCSP.	38 railroads	1 set of additional information.	400 hours	400	30,800	
236.1011(a)-(b)PTCIP content requirements	The burdens	are accounted for under 49	9 CFR 236.1009(a) a	and (e) and 236.1	021.	
(e)—Any public comment on PTCIPs, NPIs, PTCDPs, and PTCSPs.	38 railroads	2 public comments	8 hours	16	1,232	
236.1013—PTCDP and NPI content requirements	The burdens are	e accounted for under 49 (CFR 236.1009(b), (c)), and (e) and 236	.1021.	
236.1015—Any new host railroad's PTCSP meeting all content requirements under 49 CFR 236.1015.	264 railroads	1 PTCSP	8,000 hours	8,000	616,000	
(g)—A PTCSP for a PTC system replacing an existing certified PTC system.	38 railroads	0.33 PTCSPs	3,200 hours	1,056	81,312	
(h)—A quantitative risk assessment, if FRA requires one to be submitted.	38 railroads	0.33 assessments	800 hours	264	20,328	
236.1017(a)—An independent third-party assessment, if FRA requires one to be conducted and submitted.	38 railroads	0.33 assessments	1,600 hours	528	63,360	
(b)—A railroad's written request to confirm whether a specific entity qualifies as an independent third party.	38 railroads	0.33 written requests	8 hours	2.64	203	
—Further information provided to FRA upon request	38 railroads	0.33 sets of additional information.	20 hours	6.6	508	
(d)—A request not to provide certain documents otherwise required under Appendix F for an independent, third-party assessment.	38 railroads	0.33 requests	20 hours	6.6	508	
(e)—A request for FRA to accept information certified by a foreign regulatory entity for purposes of 49 CFR 236.1017 and/or 236.1009(i).	38 railroads	0.33 requests	32 hours	10.56	813	
236.1019(b)—A request for a passenger terminal main line track exception (MTEA).	38 railroads	1 MTEA	160 hours	160	12,320	
(c)(1)—A request for a limited operations exception (based on restricted speed, temporal separation, or a risk mitigation plan).	38 railroads	1 request and/or plan	160 hours	160	12,320	
(c)(2)—A request for a limited operations exception for a non-Class I, freight railroad's track.	10 railroads	1 request	160 hours	160	12,320	
(c)(3)—A request for a limited operations exception for a Class I railroad's track.	7 railroads	1 request	160 hours	160	12,320	
(d)—A railroad's collision hazard analysis in support of an MTEA, if FRA requires one to be conducted and sub- mitted.	38 railroads	0.33 collision hazard analysis.	50 hours	16.5	1,271	
(e)—Any temporal separation procedures utilized under the 49 CFR 236.1019(c)(1)(ii) exception.	The burdens are accounted for under 49 CFR 236.1019(c)(1).					
236.1021(a)-(d)-Any RFA to a railroad's PTCIP or PTCDP.	38 railroads	10 RFAs	160 hours	1,600	123,200	
(e)—Any public comments, if an RFA includes a request for approval of a discontinuance or material modification of a signal or train control system and a Federal Reg- ister notice is published.	5 interested parties	10 RFA public comments.	16 hours	160	12,320	
(I)—Any jointly filed RFA to a PTCDP or PTCSP	The burdens are accounted for under 49 CFR 236.1021(a)–(d) and (m).					
(m)—Any RFA to a railroad's PTCSP236.1023(a)—A railroad's PTC Product Vendor List, which must be continually updated.	38 railroads 38 railroads	15 RFAs2 updated lists	80 hours 8 hours	1,200 16	92,400 1,232	
(b)(1)—All contractual arrangements between a railroad and its hardware and software suppliers or vendors for certain immediate notifications.	The burdens are accounted for under 49 CFR 236.1015 and 236.1021.					
(b)(2)-(3)—A vendor's or supplier's notification, upon receipt of a report of any safety-critical failure of its product, to any railroads using the product.	10 vendors or suppliers	10 notifications	8 hours	80	6,160	

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CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual dollar cost equivalent	
		(A)	(B)	(C) = A * B	(D) = C * wage rates ²	
(c)(1)—(2)—A railroad's process and procedures for taking action upon being notified of a safety-critical failure or a safety-critical upgrade, patch, revision, repair, replace- ment, or modification, and a railroad's configuration/re- vision control measures, set forth in its PTCSP.						
(d)—A railroad's submission, to the applicable vendor or supplier, of the railroad's procedures for action upon notification of a safety-critical failure, upgrade, patch, or revision to the PTC system and actions to be taken	38 railroads	2.5 notifications	16 hours	40	3,080	
until it is adjusted, repaired, or replaced. (e)—A railroad's database of all safety-relevant hazards, which must be maintained after the PTC system is	38 railroads	38 database updates	16 hours	608	46,816	
placed in service. (e)(1)—A railroad's notification to the vendor or supplier and FRA if the frequency of a safety-relevant hazard exceeds the threshold set forth in the PTCDP and PTCSP, and about the failure, malfunction, or defective condition that decreased or eliminated the safety functionality—Form FRA F 6180.179—Errors and Mal-	38 railroads	8 notifications	7.5 hours	60	4,620	
functions Notification (Revised requirement). (e)(2)—Continual updates about any and all subsequent failures.	38 railroads	1 update	8 hours	8	616	
(f)—Any notifications that must be submitted to FRA under 49 CFR 236.1023.	The burd	lens are accounted for und	er 49 CFR 236.102	3(e), (g), and (h).		
(g)—A railroad's and vendor's or supplier's report, upon FRA request, about an investigation of an accident or service difficulty due to a manufacturing or design defect and their corrective actions.	38 railroads	0.5 reports	40 hours	20	1,540	
(h)—A PTC system vendor's or supplier's reports of any safety-relevant failures, defective conditions, previously unidentified hazards, recommended mitigation actions, and any affected railroads—Form FRA F 6180.179—Er- rors and Malfunctions Notification (Revised require- ment).	10 vendors or suppliers	20 reports	7.5 hours	150	11,550	
(k)—A report of a failure of a PTC system resulting in a more favorable aspect than intended or other condition hazardous to the movement of a train, including the re- ports required under part 233.						
236.1029(b)(4)—A report of an en route failure, other failure, or cut out to a designated railroad officer of the host railroad.	150 host and tenant railroads.	1,000 reports	30 minutes	500	38,500	
Form FRA F 6180.152—49 U.S.C. 20157(m) and 49 CFR 236.1029(h)—Quarterly Report of PTC System Performance (*Revised requirement and updated form*).	38 railroads	146 reports	32 hours	4,672	359,744	
236.1033—Communications and security requirements	The bur	dens are accounted for und	der 49 CFR 236.100	9 and 236.1015.		
236.1035(a)–(b)—A railroad's request for authorization to field test an uncertified PTC system and any responses to FRA's testing conditions.	38 railroads	10 requests	40 hours	400	30,800	
236.1037(a)(1)-(2)—Records retention	The burdens are accounted for under 49 CFR 236.1009 and 236.1015.					
(a)(3)-(4)—Records retention	The burde	ens are accounted for unde	er 49 CFR 236.1039	and 236.1043(b)		
(b)—Results of inspections and tests specified in a rail-	38 railroads	800 records	1 hour	800	61,600	
road's PTCSP and PTCDP. (c)—A contractor's records related to the testing, maintenance, or operation of a PTC system maintained at a	20 contractors	1,600 records	10 minutes	266.67	20,534	
designated office. (d)(3)—A railroad's final report of the results of the analysis and countermeasures taken to reduce the frequency of safety-related hazards below the threshold	38 railroads	8 final reports	160 hours	1,280	98,560	
set forth in the PTCSP. 236.1039(a)–(c), (e)—A railroad's PTC OMM, which must be maintained and available to FRA upon request.	38 railroads	2 OMM updates	10 hours	20	1,540	
(d)—A railroad's identification of a PTC system's safety- critical components, including spare equipment.	38 railroads	1 identified new compo- nent.	1 hour	1	77	
236.1041(a)–(b) and 236.1043(a)—A railroad's PTC Training and Qualification Program (<i>i.e.</i> , a written plan).	38 railroads	2 programs	10 hours	20	1,540	
236.1043(b)—Training records retained in a designated location and available to FRA upon request.	150 host and tenant railroads.	150 PTC training record databases.	1 hour	150	11,550	

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual dollar cost equivalent
		(A)	(B)	(C) = A * B	(D) = C * wage rates ²
Total	N/A	4,567,826 responses	N/A	51,979	4,328,077

Total Estimated Annual Responses: 4,567,826.

Total Estimated Annual Burden: 51,979 hours.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: \$4,328,077.

FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information that does not display a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520; 49 U.S.C. 20157.

Brett A. Jortland,

Deputy Chief Counsel.

[FR Doc. 2022–24723 Filed 11–10–22; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary of Transportation

[Docket No. DOT-OST-2022-0082]

Notice of Funding Opportunity To Establish Cooperative Agreements With Technical Assistance Providers for the Fiscal Year 2022 Thriving Communities Program; Correction

AGENCY: Office of the Secretary of Transportation, U.S. Department of Transportation (DOT).

ACTION: Notice of funding opportunity, correction.

SUMMARY: The Department of Transportation is correcting a notice published on October 19, 2022 issue of the Federal Register entitled "Notice of Funding Opportunity to Establish Cooperative Agreements with Technical Assistance Providers for the Fiscal year 2022 Thriving Communities Program". This notice extends the deadline date and makes minor technical corrections to the NOFO document.

SUPPLEMENTARY INFORMATION:

Corrections

In the **Federal Register** Notice of October 19, 2022, on page 63572, in the first column in the **DATES** section, the sentence, "The deadline for application submission is 11:59 p.m. Eastern Time on November 22, 2022." is corrected to read: "The deadline for application submission is 11:59 p.m. Eastern Time on November 29, 2022."

In the **Federal Register** Notice of October 19, 2022, on page 63572, in the first column in the **ACTION** section, "Notice of Funding Opportunity (NOFO), Assistance Listing # 20.942 (tentative)", is corrected to remove the word "tentative" since the Assistance Listing # 20.942 is no longer tentative and is confirmed in *SAM.gov*.

In the **Federal Register** Notice of October 19, 2022, on page 63572, in the first column in the **ADDRESSES** section, the sentence, "Applications must be submitted through *https://www.grants.gov*. Opportunity number DOT-TCP-FY22-01 (expected live date is the week of October 17, 2022)." is corrected to remove the wording "expected live date is the week of October 17, 2022", since the Opportunity number is live on *grants.gov*.

In the Federal Register Notice of October 19, 2022, on page 63576, in the third column in section 2. Content and Form of Application Submission, in the table under Forms and Supporting Documentation, "Unique Identifier and System for Award Management (SAM)" is corrected to read, "Unique Entity Identifier and System for Award Management (SAM)."

In the **Federal Register** Notice of October 19, 2022, on page 63577, in the third column in section c. Applicant Expertise, Staffing, and Project Management Plan, in the second paragraph, the sentence, "Resumes do not count against the page limit." is corrected to read, "Resumes and the one-page organization or company profile do not count against the page limit."

Issued in Washington, DC, on November 4, 2022

Christopher Coes,

Assistant Secretary for Transportation Policy, Department of Transportation.

[FR Doc. 2022–24654 Filed 11–10–22; 8:45 am] BILLING CODE 4910–9P–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Extension of Information Collection Request Submitted for Public Comment; Comment Request Relating to Electronic Payee Statements

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the 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. Currently, the IRS is soliciting comments concerning the requirements relating to electronic payee statements.

DATES: Written comments should be received on or before January 13, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments to Andrés Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov*. Please include, "OMB Number: 1545—1729—Public Comment Request Notice" in the Subject line.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the form and instructions should be directed to Ronald J. Durbala, at (202) 317–5746, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at RJoseph.Durbala@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Electronic Payee Statements. OMB Number: 1545–1729. Regulatory Number: TD 9114.

² The dollar equivalent cost is derived from the 2019 STB Full Year Wage A&B data series using the appropriate employee group hourly wage rate that includes a 75-percent overhead charge. For Executives, Officials, and Staff Assistants, this cost amounts to \$120 per hour. For Professional/ Administrative staff, this cost amounts to \$77 per hour.

Abstract: This collect contains final regulations, TD 9114 (published February 18, 2004 [69 FR 7567]), relating to the voluntary electronic furnishing of statements on Forms W-2, "Wage and Tax Statement," under sections 6041 and 6051, and statements on Forms 1098-T, "Tuition Statement," and Forms 1098-E, "Student Loan Interest Statement," under section 6050S. These final regulations affect businesses, other for-profit institutions, and eligible educational institutions that wish to furnish these required statements electronically. The regulations will also affect individuals (recipients), principally employees, students, and borrowers, who consent to receive these statements electronically.

Current Actions: There is no change to the burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other forprofit organizations.

Estimated Number of Respondents: 15.200.

Estimated Time per Respondent: 6 mins.

Estimated Total Annual Burden Hours: 2,844,950.

The following paragraph applies to all the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103

Desired Focus of Comments: The Internal Revenue Service (IRS) 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 using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: November 8, 2022.

Ronald J. Durbala,

IRS Tax Analyst.

[FR Doc. 2022–24668 Filed 11–10–22; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Extension of Information Collection Request Submitted for Public Comment; Comment Request for Forms 8609 and 8609–A

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the 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. Currently, the IRS is soliciting comments concerning Form 8609, Low-Income Housing Credit Allocation and Certification, and Form 8609–A, Annual Statement for Low-Income Housing Credit.

DATES: Written comments should be received on or before January 13, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments to Andrés Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov*. Please include, "OMB Number: 1545—0988—Public Comment Request Notice" in the Subject line.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the form and instructions should be directed to Ronald J. Durbala, at (202) 317–5746, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Form 8609, Low-Income Housing Credit Allocation Certification; Form 8609–A, Annual Statement for Low-Income Housing Credit.

OMB Number: 1545–0988. *Regulation Project Number:* Form 8609 and 8609–A.

Abstract: Owners of residential lowincome rental buildings are allowed a low-income housing credit for each qualified building over a 10-year credit period. Form 8609 can be used to obtain a housing credit allocation from the housing credit agency. A separate Form 8609 must be issued for each building in a multiple building project. Form 8609 is also used to certify certain information. Form 8609–A is filed by a building owner to report compliance with the low-income housing provisions and calculate the low-income housing credit. Form 8609-A must be filed by the building owner for each year of the 15-year compliance period. File one Form 8609–A for the allocation(s) for the acquisition of an existing building and a separate Form 8609-A for the allocation(s) for rehabilitation expenditures.

Current Actions: There are no changes to the burden previously approved by OMB

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations, not-for-profit institutions, and farms.

Estimated Number of Responses: 33.000.

Estimated Time per Respondent: 12 Hours 58 minutes.

Estimated Total Annual Burden Hours: 428,265.

The following paragraph applies to all the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Desired Focus of Comments: The Internal Revenue Service (IRS) 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 using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: November 7, 2022.

Ronald J. Durbala,

IRS Tax Analyst.

[FR Doc. 2022–24655 Filed 11–10–22; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF VETERANS AFFAIRS

VA National Academic Affiliations Council; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the VA National Academic Affiliations Council (Council) will meet virtually via conference call on December 5, 2022, from 1 p.m. to 3 p.m. Eastern Standard Time (EST). The meeting session is open to the public.

The purpose of the Council is to advise the Secretary on matters affecting partnerships between VA and its academic affiliates.

On December 5, 2022, the Council will receive project updates and have discussions on actions affecting the educational mission of VA. The Council will receive public comments from 2:50 p.m. to 2:55 p.m. EST.

Interested persons may attend and/or present oral statements to the Council. The dial in number to attend the conference call is: 669–254–5252. At the prompt, enter meeting ID 161 024 2274, then press #. The meeting passcode is

842538, then press #. Individuals seeking to present oral statements are invited to submit a 1-2 pages summary of their comments at the time of the meeting for inclusion in the official meeting record. Oral presentations will be limited to five minutes or less, depending on the number of participants. Interested parties may also provide written comments for review by the Council prior to the meeting or at any time, via email to Larissa. Emory@ va.gov, or mail to Larissa A. Emory PMP, CBP, MS, Designated Federal Officer, Office of Academic Affiliations (14AA), 810 Vermont Avenue NW, Washington, DC 20420. Any member of the public wishing to participate or seeking additional information should contact Ms. Emory via email or by phone at (915) 269-0465.

Dated: November 8, 2022.

Jelessa M. Burney,

Federal Advisory Committee Management

[FR Doc. 2022-24701 Filed 11-10-22; 8:45 am]

BILLING CODE 8320-01-P



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Part II

Department of Commerce

National Oceanic and Atmospheric Administration

Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition To List the Shortfin Mako Shark (Isurus oxyrinchus) as Threatened or Endangered Under the Endangered Species Act; Notice

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 221103-0232; RTID 0648-XR116]

Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition To List the Shortfin Mako Shark (Isurus oxyrinchus) as Threatened or Endangered Under the Endangered Species Act

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

ACTION: Notice of 12-month finding and availability of status review document for the shortfin make shark (*Isurus oxyrinchus*).

SUMMARY: We, NMFS, have completed a comprehensive status review under the Endangered Species Act (ESA) for the shortfin make shark (*Isurus oxyrinchus*) in response to a petition from Defenders of Wildlife to list the species. After reviewing the best scientific and commercial data available, including the Status Review Report, we have determined that listing the shortfin make shark as a threatened or endangered species under the ESA is not warranted.

DATES: This finding was made on November 14, 2022.

ADDRESSES: The Status Review Report associated with this determination, its references, and the petition can be accessed electronically online at: https://www.fisheries.noaa.gov/species/shortfin-mako-shark#conservation-management.

FOR FURTHER INFORMATION CONTACT: Adrienne Lohe, NMFS Office of Protected Resources, 301–427–8442.

SUPPLEMENTARY INFORMATION:

Background

On January 25, 2021, we received a petition from Defenders of Wildlife to list the shortfin mako shark (*Isurus oxyrinchus*) as a threatened or endangered species under the ESA. The petition asserted that the shortfin mako shark is threatened by four of the five ESA section 4(a)(1) factors: (1) the present or threatened destruction, modification, or curtailment of its habitat or range; (2) overutilization for commercial and recreational purposes; (3) inadequacy of existing regulatory mechanisms; and (4) other natural or manmade factors.

On April 15, 2021, NMFS published a 90-day finding for the shortfin make $\,$

shark with our determination that the petition presented substantial scientific and commercial information indicating that the petitioned action may be warranted (86 FR 19863). We also announced the initiation of a status review of the species, as required by section 4(b)(3)(A) of the ESA, and requested information to inform the agency's decision on whether this species warrants listing as endangered or threatened under the ESA. We received information from the public in response to the 90-day finding and incorporated the information into both the Status Review Report (Lohe et al. 2022) and this 12-month finding.

Listing Determinations Under the ESA

We are responsible for determining whether species are threatened or endangered under the ESA (16 U.S.C. 1531 et seq.). To be considered for listing under the ESA, a group of organisms must constitute a "species," which is defined in section 3 of the ESA to include any subspecies of fish or wildlife or plants, and any distinct population segment (DPS) of any species of vertebrate fish or wildlife which interbreeds when mature (16 U.S.C. 1532(16)). On February 7, 1996, NMFS and the U.S. Fish and Wildlife Service (USFWS; together, the Services) adopted a policy describing what constitutes a DPS of a taxonomic species ("DPS Policy," 61 FR 4722). The joint DPS Policy identifies two elements that must be considered when identifying a DPS: (1) The discreteness of the population segment in relation to the remainder of the taxon to which it belongs; and (2) the significance of the population segment to the remainder of the taxon to which it belongs.

Section 3 of the ESA defines an endangered species as any species which is in danger of extinction throughout all or a significant portion of its range and a threatened species as one which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. 1532(6), 16 U.S.C. 1532(20)). Thus, in the context of the ESA, we interpret an "endangered species" to be one that is presently in danger of extinction. A "threatened species," on the other hand, is not presently in danger of extinction, but is likely to become so in the foreseeable future. In other words, the primary statutory difference between a threatened and endangered species is the timing of when a species is in danger of extinction, either presently (endangered) or in the foreseeable future (threatened).

Under section 4(a)(1) of the ESA, we must determine whether any species is endangered or threatened as a result of any one or a combination of any of the following factors: (A) the present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence (16 U.S.C. 1533(a)(1)). We are also required to make listing determinations based solely on the best scientific and commercial data available, after conducting a review of the species' status and after taking into account efforts, if any, being made by any state or foreign nation (or subdivision thereof) to protect the species (16 U.S.C. 1533(b)(1)(A)).

Status Review

To determine whether the shortfin mako shark warrants listing under the ESA, we completed a Status Review Report, which summarizes information on the species' taxonomy, distribution, abundance, life history, and biology; identifies threats or stressors affecting the status of the species; and assesses the species' current and future extinction risk. We appointed a biologist in the Office of Protected Resources **Endangered Species Conservation** Division to compile and complete a scientific review of the best available information on the shortfin make shark, including information received in response to our request for information (86 FR 19863, April 15, 2021). Next, we convened an Extinction Risk Analysis (ERA) Team of biologists and shark experts to assess the threats affecting the shortfin mako shark, as well as demographic risk factors (abundance, productivity, spatial distribution, and diversity), using the information in the scientific review. The Status Review Report presents the ERA Team's professional judgment of the extinction risk facing the shortfin make shark but makes no recommendation as to the listing status of the species. The Status Review Report is available electronically (see ADDRESSES). Information from the Status Review Report is summarized below in the Biological Review section, and the results of the ERA from the Status Review Report are discussed below.

The Status Review Report was subject to independent peer review as required by the Office of Management and Budget Final Information Quality Bulletin for Peer Review (M–05–03; December 16, 2004). The Status Review

Report was peer reviewed by three independent specialists selected from the academic and scientific community with expertise in shark biology, conservation, and management, and specific knowledge of shortfin mako sharks. The peer reviewers were asked to evaluate the adequacy, appropriateness, and application of data used in the Status Review Report, as well as the findings made in the "Assessment of Extinction Risk" section of the report. All peer reviewer comments were addressed prior to finalizing the Status Review Report.

We subsequently reviewed the Status Review Report, its cited references, and peer review comments, and conclude the Status Review Report, upon which this 12-month finding is based, provides the best available scientific and commercial information on the shortfin mako shark. Much of the information discussed below on the species' biology, distribution, abundance, threats, and extinction risk is attributable to the Status Review Report. Following our review of the Status Review Report and consideration of peer review comments, we conclude, however, that the ERA Team's foreseeable future of 25 years for the shortfin mako shark is not adequately justified. Each of the three peer reviewers recommended evaluating the species' risk of extinction over a longer time horizon. Based on these peer review comments and our review of the ERA Team's selection of 25 years as the foreseeable future, we have completed an independent determination of the foreseeable future (see Extinction Risk Analysis). For this reason, while we rely on the ERA Team's assessment of the species' present risk of extinction, we have supplemented the assessment of the species' risk of extinction within the foreseeable future. We have also independently applied the statutory provisions of the ESA, including evaluation of the factors set forth in section 4(a)(1)(A)-(E), our regulations regarding listing determinations,1 and relevant policies identified herein in

making the 12-month finding determination.

Biological Review

Taxonomy and Species Description

The shortfin make shark belongs to the family Lamnidae in the order Lamniformes, the mackerel sharks (ITIS 2021). Lamnid sharks are littoral to epipelagic with broad distributions in tropical to cold-temperate waters (Compagno 1984). They are fastswimming and have a modified circulatory system to maintain internal temperatures warmer than the surrounding water (Compagno 1984). The shortfin make shark belongs to the genus Isurus and only has a single living cogeneric species, the longfin make shark (Isurus paucus). The species is relatively large, reaching a maximum total length (TL) of about 445 centimeters (cm) (Weigmann 2016), and has a moderately slender, spindleshaped body with a conical snout (Compagno 1984). Its pectoral fins are narrow-tipped and moderately broad and long (considerably shorter than the length of the head) as compared to the very long pectoral fins of the longfin mako shark, which also has a less pointed snout and dusky underside (Compagno 1984; Ebert *et al.* 2013). The first dorsal fin is large and the second is very small and pivoting (Compagno 1984). The upper and lower lobes of the caudal fin are of nearly equal size, which is reflected in the genus name Isurus from the Greek words for "equal tail." The teeth are large and bladelike without serrations, and the tips of the anterior teeth are strongly reflexed (Compagno 1984). The dorsal surface of the body is dark blue and the ventral side is white (Compagno 1984).

Distribution

The shortfin make shark is a globally distributed pelagic species, occurring across all temperate and tropical ocean waters from about 50° N (up to 60° N in the northeast Atlantic) to 50° S and across a range of marine habitats (Rigby et al. 2019; Santos et al. 2020). Compagno (2001) provides the following description of the species' global distribution: in the western Atlantic, the species occurs from the Gulf of Maine to southern Brazil and possibly northern Argentina, including Bermuda, the Caribbean, and the Gulf of Mexico. In the eastern Atlantic, the range spans from Norway, the British Isles, and the Mediterranean to Morocco, Azores, Western Sahara, Mauritania, Senegal, Côte d'Ivoire, Ghana, southern Angola, probably Namibia, and the west coast of South

Africa. In the Indo-Pacific basin, the species is found from the east coast of South Africa, Mozambique, Madagascar, Mauritius and Kenya north to the Red Sea, and east to Maldives, Iran, Oman, Pakistan, India, Indonesia, Viet Nam, China, Taiwan, North Korea, South Korea, Japan, Russia, Australia (all states and entire coast except for Arafura Sea, Gulf of Carpentaria and Torres Strait), New Zealand (including Norfolk Island), New Caledonia, and Fiji. In the central Pacific, the shortfin mako shark occurs from south of the Aleutian Islands to the Society Islands, including the Hawaiian Islands, and in the eastern Pacific, from southern California (and sometimes as far north as Washington State) south to Mexico, Costa Rica, Ecuador, Peru, and central Chile. Rare observations outside of this range have also been made, for example in waters of British Columbia (Gillespie and Saunders 1994).

Habitat Use

The shortfin make shark is known to travel long distances in and between open ocean, continental shelf, shelf edge, and shelf slope habitats (Rogers et al. 2015b; Santos et al. 2021), making extensive long-distance straight-line movements of several thousand kilometers (km) (Francis et al. 2019). From traditional dart and fin tagging data, maximum recorded time at liberty is 12.8 years, and the maximum straightline distance between tag and recapture localities is 3,043 nautical miles (5,636 km) (Kohler and Turner 2019). Shorterterm electronic tagging results from several studies indicate that the species commonly makes roundtrip migratory movements of more than 20,000 km, with one individual found to undertake an extended migration of 25,550 km over a period of 551 days (Rogers et al. 2015b; Francis et al. 2019). While the species has also demonstrated fidelity to small geographic areas on or near continental shelves and coastal areas of high productivity, this fidelic behavior is rarely observed in the open ocean (Rogers et al. 2015b; Corrigan et al. 2018: Francis et al. 2019: Gibson et al. 2021). Recent research demonstrates that the species regularly switches between these states of activity (i.e., resident or fidelity behavior state and traveling state), spending nearly half their time (44–47 percent) in residency and slightly less than half their time (35-42 percent) in transit (Rogers et al. 2015b; Francis et al. 2019). It is unknown whether these behavioral states are tied to specific behaviors such as feeding or breeding. Furthermore, this behavioral switching may be affected by factors including

On July 5, 2022, the United States District Court for the Northern District of California issued an order vacating the ESA section 4 implementing regulations that were revised or added to 50 CFR 424 in 2019 ("2019 regulations," see 84 FR 45020, August 27, 2019) although making no findings on the merits. On September 21, 2022, the U.S. Court of Appeals for the Ninth Circuit granted a temporary stay of the district court's July 5 order. As a result, the 2019 regulations are once again in effect, and we are applying the 2019 regulations here. For purposes of this determination, we considered whether the analysis or its conclusions would be any different under the pre-2019 regulations. We have determined that our analysis and conclusions presented here would not be any

environmental variation, spatial areas of sampling, or biotic factors; therefore, these findings may not be representative of the entire species, especially across time and space.

The vertical distribution of shortfin mako sharks is related to numerous environmental variables, including water temperature, dissolved oxygen (DO) concentration, time of day, prey availability, and lunar phase. The species typically occupies waters ranging between 17 °C and 22 °C (Casey and Kohler 1992; Nasby-Lucas et al. 2019; Santos et al. 2020, 2021), though it has a broad thermal tolerance and has been shown to also occupy waters from 10 °C (Abascal et al. 2011) to 31 °C (Vaudo et al. 2017). Like other lamnid sharks, the shortfin make shark has counter-current circulation and is a red muscle endotherm, meaning that it can maintain the temperature of its slowtwitch, aerobic red muscle significantly above ambient temperature (Watanabe et al. 2015). Red muscle endothermy allows the species to tolerate a greater range of water temperatures, cruise faster, and have greater maximum annual migration lengths than fish without this trait (Watanabe *et al.* 2015). The high energetic cost of endothermy is suggested to be outweighed by benefits such as increased foraging success, prey encounter rates, and access to other seasonally available resources (Watanabe et al. 2015). The routine metabolic rate and maximum metabolic rate of shortfin make sharks is among the highest measured for any shark species (Sepulveda et al. 2007), which may explain why the shortfin mako shark typically inhabits waters with DO concentrations of at least 3 milliliters per liter and avoids areas of low DO (Abascal et al. 2011). Individuals primarily occupy the upper part of the water column, but dive to depths of several hundred meters (m) (as deep as 979.5 m reported by Santos et al. (2021)), allowing them to forage for mesopelagic fishes and squid, though dives may have other functions including navigation (Holts and Bedford 1993; Francis et al. 2019). There is evidence that illumination from a full moon causes shortfin make sharks to move into deeper water in pursuit of prey (Lowry et al. 2007). "Bounce" or 'yo-yo'' diving behavior, in which individuals repeatedly descend to deeper water and then ascend to shallow depths, has been regularly observed in both adults and young-ofthe-year (YOY) (Sepulveda et al. 2004; Abascal et al. 2011; Vaudo et al. 2016; Santos et al. 2021). This type of diving behavior may be associated with

feeding, behavioral thermoregulation, energy conservation, and navigation (Klimley et al. 2002; Sepulveda et al. 2004). Tagging studies have shown that the species typically spends more time in deeper, colder water during the daytime, and moves to shallower, warmer waters at night (Holts and Bedford 1993; Klimley et al. 2002; Sepulveda et al. 2004; Loefer et al. 2005; Stevens et al. 2010; Abascal et al. 2011; Nasby-Lucas et al. 2019). These diel vertical migrations are typically attributed to the pursuit of prey. However, other studies indicate no significant changes in vertical distribution between daytime and nighttime (Abascal et al. 2011, Santos et al. 2020). Larger individuals can dive to deeper depths than smaller individuals (Sepulveda et al. 2004), and juveniles specifically tend to spend much of their time in shallower, warmer water (Holts and Bedford 1993; Nosal et al. 2019).

There is some evidence that certain ocean currents and features may limit movement patterns, including the Mid-Atlantic ridge separating the western and eastern Atlantic (Casey and Kohler 1992 using conventional tagging data from 231 recaptured shortfin make sharks over a 28-year period; Santos et al. 2020 using satellite telemetry for 41 shortfin mako sharks over a period of between 30 and 120 days), and the Gulf Stream separating the North Atlantic and the Gulf of Mexico/Caribbean Sea (Vaudo et al. 2017 using satellite telemetry for 26 shortfin make sharks over a period of 78-527 days). However, conventional tagging data indicates that movement does occur across these features. Data from the NMFS Cooperative Shark Tagging Program (n=1,148 recaptured shortfin make sharks) over a 52-year period show evidence of the species crossing the Mid-Atlantic Ridge demonstrating exchange between the western and eastern Atlantic (Kohler and Turner 2019). In fact, individual shortfin mako sharks (n = 104) that made long distance movements (>1,000 nautical miles) while at liberty for less than one year were primarily tagged off the coast of the U.S. Northeast and were recaptured in the Gulf of Mexico, Caribbean Sea, mid-Atlantic Ocean, and off Portugal, Morocco, and Western Sahara (Kohler and Turner 2019). In the Pacific, tagging data supports east-west mixing in the north and minimal east-west mixing in the south (Sippel et al. 2016 using conventional tagging data from 704 recaptured shortfin make sharks since 1968; Corrigan et al. 2018 using satellite telemetry data of 13 individuals over a period of 249-672 days). Transequatorial movement appears to be uncommon based on tagging studies (Sippel *et al.* 2016; Corrigan *et al.* 2018), but tagged shortfin make sharks have been recorded crossing the equator (Rogers et al. 2015a; Santos *et al.* 2021).

The locations of mating grounds and other reproductive areas are not well known for the shortfin make shark, although the distribution of the youngest age classes may indicate potential pupping and nursery areas. Casey and Kohler (1992) observed YOY shortfin mako sharks offshore in the Gulf of Mexico, hypothesizing that pups are born offshore in the Northwest Atlantic to protect them from predation by large sharks, including other makos. Bite marks observed on mature females caught in the Gulf of Mexico may have resulted from mating behavior, indicating that the area may also be a mating ground (Gibson et al. 2021). The presence of mature and pregnant females in the Gulf of Mexico provides further support that this may be a gestation and parturition ground for the species. However, fisheries data suggests that pupping is geographically widespread in the Northwest Atlantic given that neonates are widely distributed along the coast of North America and largely overlap with the distribution of older immature sharks and adults (Natanson et al. 2020). Excursions of tagged shortfin make sharks towards the shelf and slope waters of the Subtropical Convergence Zone, the Canary archipelago, and the northwestern African continental shelf, as well as aggregations of YOY shortfin mako sharks in these areas, may indicate that they serve as pupping or nursery grounds in the Northeast Atlantic (Maia et al. 2007; Natanson et al. 2020; Santos et al. 2021). In the Eastern North Pacific, the Southern California Bight has been suggested as a nursery area as roughly 60 percent of the catch here is made up by YOY and 2- to 4-year-old juveniles (Holts and Bedford 1993; Rodríguez-Madrigal et al. 2017; Nasby-Lucas et al. 2019). Farther south, the presence of many juveniles and some neonates near fishing camps in Baja California, Mexico, suggests that the area between Bahía Magdalena and Laguna San Ignacio may also be a nursery ground for the shortfin make shark (Conde-Moreno and Galvan-Magana 2006). Presence of small immature shortfin mako sharks off Caldera, Chile, suggests that this may be a pupping or nursery area for the Southeastern Pacific (Bustamante and Bennett 2013). The temperate waters of the south-west Indian Ocean have been shown to host high concentrations of

neonates and adults, suggesting that this area may be a nursery ground (Wu et al. 2021). Further, pregnant females have been observed in coastal waters off South Africa, strengthening the evidence that this area may be used for pupping or as a nursery (Groeneveld et al. 2014).

Diet and Feeding

The shortfin make shark is a large, active predator that feeds primarily on teleosts and also consumes cephalopods, other elasmobranchs, cetaceans, and crustaceans (Stillwell and Kohler 1982; Cortés 1999; Maia et al. 2006; Gorni et al. 2012). It is estimated that shortfin make sharks must consume 4.6 percent of their body weight per day to meet their high energetic demands (Wood *et al.* 2009). Based on the shortfin make shark's diet, the species has a trophic level of 4.3 out of 5.0 (tertiary consumers have a trophic level over 4.0, while plants have a trophic level of one), one of the highest of 149 species examined by Cortés (1999) and comparable to other pelagic shark species such as common and bigeye thresher sharks (Alopias vulpinus and Alopias superciliosus), the salmon shark (Lamna ditropis), and the oceanic whitetip shark (Carcharhinus longimanus) (Bizzarro et al. 2017). Rogers et al. (2012) found evidence that the species targets specific prey despite high prey diversity; however, stable isotope analysis indicates that the species is a generalist predator (Maya Meneses et al. 2016). The degree of prev selectivity in any given individual's diet is likely strongly correlated with prey availability, with prey being consumed as encountered.

The specific diet of the shortfin make shark varies by life stage, geographic location, season, and oceanic habitat. In the Northwest Atlantic, bluefish (Pomatomus saltatrix) are a major inshore prey item for the species and have been estimated to make up 77.5 percent of diet by volume (Stillwell and Kohler 1982), and more recently, 92.6 percent of diet by weight (Wood et al. 2009). In the northeast Atlantic, teleosts made up over 90 percent of the species' diet by weight, and Clupeiformes and garpike (Belone belone) are common prey (Maia et al. 2006). In the South Atlantic, teleosts are also dominant in the shortfin mako shark's diet (including Lepidocibium flavobruneum, Scomber colias, and Trichiruridae), while cephalopods of the orders Teuthida and Octopoda are also consumed (Gorni et al. 2012). In the northeast Pacific along the west coast of the United States, jumbo squid (Dosidicus gigas) and Pacific saury

(Cololabis saira) are the two most important previtems, and other frequent teleost prey includes Pacific sardine (Sardinops sagax), Pacific mackerel (Scomber japonicus), jack mackerel (Trachurus symmetricus), and striped mullet (Mugil cephalus) (Preti et al. 2012). By contrast, YOY and juvenile shortfin mako sharks off Baja California Sur, Mexico, largely consume whitesnout searobin (Prionotus albirostris), Pacific mackerel (S. japonicus), and a variety of small squids (Velasco Tarelo 2005). As they age, larger teleost species and squids more commonly found in offshore pelagic waters become increasingly important, as evidenced by stable isotope analysis (Velasco Tarelo 2005). A large female shortfin mako shark recreationally caught off the coastline of the Southern California Bight was found to have eaten a California sea lion, Zalophus californianus, an event that does not appear uncommon based on previously documented pinnipeds in the stomachs of large shortfin mako sharks (Lyons et al. 2015). Shortfin make sharks in the Indian Ocean prey on teleosts (Trachurus capensis and S. sagax), elasmobranchs (Rhizoprionodon acutus and Carcharhinus obscurus), and cephalopods (Loligo spp.) (Groeneveld et al. 2014). The dominant prey of shortfin mako sharks caught in coastal bather protection nets in the southwest Indian Ocean were elasmobranchs, while the diet of shortfin make sharks caught in offshore longlines was dominated by teleosts (Groeneveld et al. 2014). As the size of individuals caught in coastal bather nets was significantly greater than those caught in offshore longlines, Groeneveld et al. (2014) suggest that larger prey attracts larger mako sharks to coastal waters.

Size and Growth

Shortfin make sharks are long-lived, and are estimated to reach maximum ages of at least 28-32 years based on vertebral band counts validated by bomb radiocarbon and tag-recapture studies (Natanson et al. 2006; Dono et al. 2015). Longevity in the Pacific has been estimated as high as 56 years (Chang and Liu 2009; Carreon-Zapiain et al. 2018). There is uncertainty in the use of vertebral band pair counting to determine age as some authors find evidence for or assume annual growth band deposition periodicity (Cailliet et al. 1983; Campana et al. 2002; Ardizzone et al. 2006; Bishop et al. 2006; Semba et al. 2009; Dono et al. 2015; Liu et al. 2018) while others find evidence for the deposition of two growth band pairs each year for either all (Pratt Jr. and Casey 1983) or their

first five years of life (Wells et al. 2013). Kinney et al. (2016) used the recapture of an oxytetracycline-tagged adult male to validate annual band deposition in adult shortfin make sharks, inferring that juveniles experience more rapid growth and, therefore, exhibit biannual band pair deposition. In addition, there is evidence that vertebral band pair counts do not accurately reflect age in older, large individuals (Harry 2018; Natanson et al. 2018). Due to inconsistent information on vertebral band deposition in the Pacific, the International Scientific Committee for Tuna and Tuna-like Species (ISC) Shark Working Group's 2018 stock assessment of shortfin mako sharks in the North Pacific treated data from the western North Pacific as having a constant band pair deposition rate and data from the eastern North Pacific as having a band pair deposition rate that changes from two to one band pairs per year after age 5. The 2017 stock assessment of North and South Atlantic shortfin make sharks conducted by the International Commission for the Conservation of Atlantic Tunas (ICCAT) assumed annual band pair deposition based on Natanson et al. (2006).

Shortfin mako sharks exhibit slow growth rates. Growth coefficient (K) estimates range from 0.043-0.266 year⁻¹ in the Atlantic Ocean, 0.0154-0.16 year⁻¹ in the Pacific Ocean, and 0.075-0.15 year -1 in the Indian Ocean (Pratt Jr. and Casey 1983, Ribot-Carballal et al. 2005, Natanson et al. 2006, Bishop et al. 2006, Cerna and Licandeo 2009, Semba et al. 2009, Groeneveld et al. 2014, Liu et al. 2018). Males and females have similar growth rates until a certain point, when male growth slows down compared to female growth. This has been estimated to occur at 7 years of age in the western and central North Pacific (Semba et al. 2009), 11 years of age in the Northwest Atlantic (Natanson et al. 2006), and 15 years of age (217 cm fork length (FL)) in the western South Atlantic (Dono et al. 2015). Females ultimately attain larger sizes than males, as has been documented in other shark species (Natanson et al. 2006). Maximum theoretical length in females is reported to be 370 cm TL in the western and central North Pacific (Semba et al. 2009) and 362 cm TL in the eastern North Pacific (Carreon-Zapiain et al. 2018). The maximum observed length for the species is 445 cm TL (Weigmann 2016), although Kabasakal and de Maddalena (2011) used photographs to estimate the length of a female caught off Turkey at 585 cm TL.

Age and size at maturity vary by geographic location. In general, males

and females reach maturity at approximately 6–9 and 15–21 years (Natanson et al. 2006; Semba et al. 2009), and at sizes of 180–222 cm TL and 240–289 cm TL (Conde-Moreno and Galvan-Magana 2006; White 2007; Varghese et al. 2017), respectively. Additional information on growth and reproductive parameters for the species can be found in Table 1 of the Status Review Report.

Reproductive Biology

Shortfin mako sharks reproduce through oophagous (meaning 'egg eating') vivipary, wherein, after depletion of their yolk-sac, the embryos develop by ingesting unfertilized eggs inside the mother's uterus and are born as live young (Stevens 1983; Mollet et al. 2000). Estimates of gestation time vary from nine months to 25 months (Mollet et al. 2000; Duffy and Francis 2001; Joung and Hsu 2005; Semba et al. 2011) and litter sizes typically range from four to 25 pups (Mollet et al. 2000; Joung and Hsu 2005; Semba et al. 2011). Several studies find that litter size increases with maternal size (Mollet et al. 2000; Semba et al. 2011), though others find no evidence of this relationship (Joung and Hsu 2005; Liu et al. 2020). Size at birth is approximately 70 cm TL (Mollet et al. 2000). The reproductive cycle is estimated to take up to 3 years, with a potential resting period of 18 months (Mollet et al. 2000). There is evidence that parturition (birth) occurs in late winter to mid-spring in both the Northern and Southern Hemispheres based on embryonic growth estimates (Mollet et al. 2000; Semba et al. 2011; Bustamante and Bennett 2013), though Duffy and Francis (2001) found evidence of parturition in summer. With regard to mating strategy, two studies have found genetic evidence for polyandry and multiple paternity within litters, though other mating strategies (e.g., polygyny or monogamy) cannot be ruled out (Corrigan et al. 2015; Liu et al. 2020).

Population Structure and Genetics

Although certain ocean currents and features may limit movement patterns between different regions as discussed previously (see *Habitat Use*), several genetic studies indicate a globally panmictic (characterized by random mating) population with some genetic structuring among ocean basins.

Heist *et al.* (1996) investigated population structure using restriction fragment length polymorphism analysis of maternally inherited mitochondrial DNA (mtDNA) from shortfin mako sharks in the Northwest Atlantic (n = 21), central North Atlantic (n = 24),

western South Atlantic (n = 23), eastern North Pacific (n = 30), and western South Pacific (n = 22). The North Atlantic samples showed significant isolation from other regions (p < 0.001) and differed from other regions by the relative lack of rare and unique haplotypes and high abundance of a single haplotype (Heist et al. 1996). Significant differences in haplotype frequencies were not detected between the samples from Brazil, Australia, and California (Heist et al. 1996). Haplotypes did not seem to be confined to specific regions, and the three most common haplotypes were found in all samples (Heist et al. 1996). Clustering of mtDNA haplotypes did not initially support the presence of genetically distinct stocks of shortfin make shark (Heist et al. 1996); however, reanalysis of the data found significant differentiation between the South Atlantic and North Pacific samples (Schrey and Heist 2003) in addition to isolation of the North Atlantic.

A microsatellite analysis of samples from the North Atlantic (n = 152), South Atlantic (Brazil; n = 20), North Pacific (n = 192), South Pacific (n = 43), and Atlantic and Indian coasts of South Africa (n = 26) found very weak evidence of population structure (F_{ST} = 0.0014, P = 0.1292; $R_{ST} = 0.0029$, P =0.019) (Schrey and Heist 2003). Pairwise F_{ST} comparisons were not statistically significant after Bonferroni correction, though one pairwise R_{ST} value (North Atlantic vs. North Pacific) showed significant differentiation ($R_{ST} = 0.0106$, P = 0.0034). These results were insufficient to reject the null hypothesis of a single genetic stock of shortfin mako shark, suggesting that there is sufficient movement of shortfin mako sharks, and therefore gene flow, to reduce genetic differentiation between regions (Schrey and Heist 2003). The authors note that their findings conflict with the significant genetic structure revealed through mtDNA analysis by Heist et al. (1996). They suggest that as mtDNA is maternally inherited and nuclear DNA is inherited from both parents, population structure shown by mtDNA data could indicate that female shortfin mako sharks exhibit limited dispersal and philopatry to parturition sites, while male dispersal allows for gene flow that would explain the results from the microsatellite data (Schrev and Heist 2003).

Taguchi et al. (2011) analyzed mtDNA samples from the central North Pacific (n = 39), western South Pacific (n = 16), eastern South Pacific (n = 10), North Atlantic (n = 9), eastern Indian Ocean (n = 16), and western Indian Ocean (n = 16), finding evidence of significant

differentiation between the North Atlantic, and the central North Pacific and eastern South Pacific (pairwise Φ_{ST} = 0.2526 and 0.3237, respectively). Interestingly, significant structure was found between the eastern Indian Ocean and the Pacific Ocean samples (pairwise Φ_{ST} values for Central North Pacific, Western South Pacific, Eastern South Pacific are 0.2748, 0.1401, and 0.3721, respectively), but not between the eastern Indian and the North Atlantic (Taguchi *et al.* 2011).

Corrigan et al. (2018) also found evidence of matrilineal structure from mtDNA data, while nuclear DNA data provide support for the existence of a globally panmictic population. Although there was no evidence of haplotype partitioning by region and most haplotypes were found across many (sometimes disparate) locations, Northern Hemisphere sampling locations were significantly differentiated from all other samples, suggesting reduced matrilineal gene flow across the equator (Corrigan et al. 2018). The only significant differentiation indicated by microsatellite data was between South Africa and southern Australia (pairwise $F_{ST} = 0.037$, $\Phi_{ST} = 0.043$) (Corrigan *et al.* 2018). Clustering analysis showed only minor differences in allele frequencies across regions and little evidence of population structure (Corrigan et al. 2018). Overall, the authors conclude that although spatial partitioning exists, the shortfin make shark is genetically homogenous at a large geographic scale. Taken together, results of genetic analyses suggest that female shortfin mako sharks exhibit fidelity to ocean basins, possibly to utilize familiar pupping and rearing grounds, while males move across the world's oceans and mate with females from various basins, thereby homogenizing genetic variability (Heist et al. 1996; Schrey and Heist 2003; Taguchi et al. 2011; Corrigan et al. 2018).

Haplotype diversity in shortfin mako sharks has been found to be high in several studies. Heist et~al.~(1996) found 25 haplotypes among 120 individuals for an overall haplotype diversity of 0.755 and a nucleotide diversity of 0.347. Taguchi et~al.~(2011) found haplotype and nucleotide diversity to be 0.92 and 0.0070, respectively, across the global range of the species. Corrigan et~al.~(2018) detected 48 unique haplotypes among 365 individuals for a haplotype diversity of 0.894 \pm 0.013 and found very low nucleotide diversity of 0.004 \pm 0.003.

Demography

Natural mortality for shortfin mako sharks is low and was estimated by Bishop et al. (2006) at 0.14 and 0.15 year⁻¹ for males and females, respectively. Chang and Liu (2009) calculated natural mortality at 0.077–0.244 year⁻¹ for females and 0.091–0.203 year⁻¹ for males in the Northwest Pacific. In the North Atlantic, natural mortality was estimated at 0.101 year⁻¹ (Bowlby et al. 2021). The generation time is estimated at 25 years (Cortés et al. 2015; Rigby et al. 2019).

In an analysis of productivity and susceptibility to longline fisheries in the Indian Ocean, Murua et al. (2018) calculated a population finite growth rate (λ) for shortfin make sharks of 1.049 year⁻¹ (1.036–1.061; Murua *et al.* 2018). Liu et al. (2015) estimated values for λ of shortfin mako sharks off California to be 1.1213 ± 0.0635 year⁻¹ and $1.0300 \pm$ 0.0763 year⁻¹ for those in the Northwest Pacific. As the species displays sexual dimorphism in size, growth rates, and size at maturity, Tsai et al. (2015) argue that the use of a twosex demographic model more accurately estimates the probability of decline risk and, therefore, better informs management decisions. Further, as the mating mechanism of shortfin mako sharks affects the proportion of breeding females and has not been conclusively established, these scenarios (monogamous, polyandrous, polygynous) should be modeled as well (Tsai et al. 2015). The authors report that in the Northwest Pacific, without fisheries-related mortality, values for λ were 1.047, 1.010, and 1.075 year⁻¹ for females and 1.056, 1.011, and 1.090 year⁻¹ for males in monogamous, polyandrous, and polygynous mating scenarios, respectively. Under fishing conditions at the time of the study, all values for λ dropped to less than one $(0.943, 0.930, and 0.955 year^{-1} for$ females and 0.918, 0.892, and 0.939 year⁻¹ for males in monogamous, polyandrous, and polygynous mating scenarios, respectively). Thus, population declines were expected regardless of the mating system modeled.

Productivity for the shortfin mako shark is quite low. In a recent analysis using six methods, Cortés (2016) determined that the intrinsic rate of population increase (r_{max}) for Atlantic shortfin mako sharks ranged from 0.036–0.134 yr $^{-1}$. These values were among the lowest calculated from 65 populations and species of sharks (Cortés 2016).

Abundance and Trends

Currently, there is no estimate of the absolute global abundance of the shortfin mako shark; however, based on the age-structured assessments conducted by ICCAT (2017) and the ISC Shark Working Group (2018), current abundance is estimated to be one million individuals in the North Atlantic and eight million individuals in the North Pacific (FAO 2019). Comprehensive analyses based on available regional stock assessments and standardized catch-per-unit-effort (CPUE) data have been used by the International Union for Conservation of Nature (IUCN) to approximate trends for the species globally.

In the 2019 IUCN Red List assessment, Rigby et al. estimated a global population trend using the following data sources: (1) the 2017 stock assessments conducted by ICCAT for the North and South Atlantic, (2) the 2018 stock assessment conducted by the ISC Shark Working Group for the North Pacific, (3) standardized CPUE data for the South Pacific from Francis et al. (2014), and (4) a preliminary stock assessment in the Indian Ocean by Brunel *et al.* (2018). Individual trends by region are discussed below. Using Just Another Red List Assessment (JARA) (Winker et al. 2018; Sherley et al. 2019), a Bayesian state-space tool for trend analysis of abundance indices, Rigby et al. (2019) found that the species is declining in all oceans other than the South Pacific, where it is increasing, with the steepest population declines indicated in the North and South Atlantic. Due to the unreliable stock assessment in the South Atlantic (discussed further below), Rigby et al. (2019) considered the North Atlantic stock assessment to be representative of the South Atlantic for the trend analysis. However, this may have inaccurately represented the extent of decline in the South Atlantic; the North Atlantic has experienced the largest known degree of decline across the species' range, and while there is some possibility that the South Atlantic has a similar stock status, the 2017 stock assessment does not support that conclusion, and accordingly, ICCAT has not taken comparable regulatory action for the species in the South Atlantic. A global trend was estimated by weighting each region's trend by the relative size of each region. To standardize the time period over which the trends were calculated, JARA projected forward the amount of years without observations that it would take to reach three generation lengths. The overall median population reduction was estimated at

46.6 percent, with the highest probability of 50-79 percent reduction over three generation lengths (72–75 years). Because available datasets for each region cover different time periods and have different durations, the timeframe of this trend is not a comparison between two specific years, but rather a standardized timeframe of three generation lengths. Trends indicated by Rigby et al. (2019) do not always align with abundance and trend indicators from other sources, as discussed below. The JARA framework used by Rigby et al. (2019) has been described as inappropriate for this longlived, sexually dimorphic species because it only uses mean annual trends in the population over the assessment period and does not consider size or age structures of the population over recent decades (Kai 2021a). Available information on abundance and trends by region is discussed below. Stock assessments provide information on the status of a stock, with results presented using the terms "overfished" and "overfishing." Specific to the context of the Magnuson-Stevens Fishery Conservation and Management Act (MSA), a stock or stock complex is considered "overfished" when its biomass has declined below minimum stock size threshold (MSST), defined as the level of biomass below which the capacity of the stock or stock complex to produce maximum sustainable vield (MSY) on a continuing basis has been jeopardized (50 CFR 600.310(e)(2)(E)-(F)). Overfishing occurs whenever a stock or stock complex is subjected to a level of fishing mortality or total catch that jeopardizes the capacity of a stock or stock complex to produce MSY on a continuing basis (50 CFR 600.310(e)(2)(B)). While the stock assessments referenced in this finding do not define "overfished" and "overfishing" using the exact language above, they use the two terms with equivalent meanings. It is important to note that the terms "overfished" and "overfishing" do not have any specific relationship to the terms "threatened" or "endangered" as defined in the ESA. While a stock that is overfished is not able to sustain an exploitive fishery at MSY (i.e., the highest possible annual catch that can be sustained over time), there is a significant difference between a stock that is overfished and a stock that is in danger of extinction. A stock will become overfished long before it is threatened with extinction, and can be stable at biomass levels that do not support MSY. Similarly, one goal of the MSA (and fisheries management organizations) is to "rebuild" overfished

stocks to biomass levels that will support MSY. This level can be significantly above the biomass levels necessary to ensure that a species is not in danger of extinction. Thus, evidence of declining abundance that threatens the ability of the fishery to provide MSY are relevant, but not dispositive of a threatened or endangered species determination. Therefore, while available information about whether specific stocks are overfished or experiencing overfishing is relevant to and considered in our ESA extinction risk analysis, the fact that a stock may be considered "overfished" or experiencing "overfishing" does not automatically indicate that any particular status is appropriate under the ESA. Stock assessments, which provide information for determining the sustainability of a fishery, are based on different criteria than status reviews conducted under the ESA, which provide information to assess the likelihood of extinction of the species. When conducting a status review under the ESA, we use relevant information from available stock assessments, such as levels of biomass and fishing mortality, and apply the ESA's definitions of threatened and endangered species to the information in the record using our standard tools of ESA extinction risk analysis. As part of our ESA extinction risk analysis, when examining whether overutilization for commercial purposes is a threat to the species, we consider whether the species has been or is being harvested at levels that contribute to or pose a risk of extinction to the species.

North Atlantic Ocean

The most recent stock assessment by ICCAT indicates a combined 90 percent probability that the North Atlantic stock is in an overfished state and is experiencing overfishing (ICCAT 2017). The nine model runs used in this assessment generally agreed, indicating that stock abundance in 2015 was below biomass at maximum sustainable yield (B_{MSY}) (ICCAT 2017). The agestructured stock assessment model estimates historical declines in spawning stock fecundity (SSF, defined as the number of pups produced in each year) from 1950 (unfished condition) to 2015 at 50 percent and recent declines (from 2006 to 2015) at 32 percent (FAO 2019). All assessment models were consistent, and together indicated that the North Atlantic shortfin make shark has experienced historical declines in total biomass of between 47-60 percent, and recent declines in total biomass of between 23-32 percent (FAO 2019). Projections conducted in the 2017

assessment using a production model estimated that for a total allowable catch (TAC; in this case, TAC refers to all sources of mortality and is not limited to landings data) of 1,000 metric tons (t), the probability of the stock being rebuilt and not experiencing overfishing (biomass (B) > B $_{\rm MSY}$, and fishing mortality (F) < fishing mortality at MSY (F $_{\rm MSY}$)) was only 25 percent by 2040 (one generation length).

In 2019, the ICCAT Standing Committee on Research and Statistics (SCRS) carried out new projections for North Atlantic shortfin make shark through 2070 (two generation lengths) using an integrated model (Stock Synthesis) at the Commission's request. The 2019 update to the stock assessment projects that even with a zero TAC, the North Atlantic stock would have a 53 percent probability of being rebuilt (SSF > SSF_{MSY}) and not experiencing overfishing (F < F_{MSY}) by 2045, and that regardless of TAC (including a TAC of 0 t), the stock will continue declining until 2035 (ICCAT 2019). Projections showed that a TAC of 500 t has a 52 percent probability of rebuilding the stock, with overfishing not occurring, by 2070. The projections indicated that realized TAC must be 300 t or less to ensure that the stock will be rebuilt and not experiencing overfishing with at least a 60 percent probability by 2070 (ICCAT 2019). These TAC options with associated time frames and probabilities of rebuilding were presented to the Commission; however, given the vulnerable biological characteristics of this stock and these pessimistic projections, to accelerate the rate of recovery and to increase the probability of success, the SCRS recommended that the Commission adopt a non-retention policy without exception.

The 2017 stock assessment and 2019 update to the stock assessment present more accurate and rigorous results than the prior 2012 assessment. The 2012 assessment overestimated stock size, underestimated fishing mortality, and suggested a low probability of overfishing (ICCAT 2019). Input data and model structure changed significantly between the 2012 and 2017 ICCAT stock assessments: catch time series start earlier (1950 vs. 1971 in the 2012 assessment), some biological inputs have changed and are sexspecific in the 2017 assessment, and additional length composition data became available (ICCAT 2017). In addition, the CPUE series have been decreasing since 2010, which was the last year in the 2012 assessment models (ICCAT 2017). Finally, the agestructured model in the 2017 stock assessment more accurately captured

the time-lags in population dynamics of a long-lived species than the production models used in 2012.

The IUCN's JARA trend analysis for the North Atlantic region relied on the 2017 ICCAT stock assessment. Trend analysis of modeled biomass estimated a median decline of 60 percent in the North Atlantic based on annual rates of decline of 1.2 percent between 1950 and 2017 (Rigby et al. 2019), which is consistent with the decrease in total biomass (60 percent) obtained from Stock Synthesis model run 3 from the 2017 ICCAT stock assessment.

There is no stock assessment available for shortfin make sharks in the Mediterranean Sea. Ferretti et al. (2008) compiled data from public and private archives representing sightings, commercial fisheries, and recreational fisheries data in the western Mediterranean Sea and used generalized linear models to conduct a metaanalysis of encounter trends. Long-term combined trends for shortfin mako shark and porbeagle (Lamna nasus) in the Mediterranean Sea indicate up to a 99.99 percent decrease in abundance and biomass since the early 19th century, though there was considerable variability among datasets due to geography and sample size (Ferretti et al. 2008). While shortfin make sharks spanning a broad range of sizes (suggesting breeding/pupping in the region) are occasionally reported as bycatch in swordfish and albacore longline fisheries (Megalofonou et al. 2005), or in other artisanal or commercial fisheries (Kabasakal 2015), from the eastern Mediterranean Sea, no reliable estimates of abundance are available for this region.

Overall, the best available scientific and commercial information indicates that the North Atlantic shortfin mako shark population has experienced historical declines in biomass of between 47 and 60 percent, and declines will continue until at least 2035 regardless of fishing mortality.

South Atlantic Ocean

Results of the most recent ICCAT stock assessment for shortfin mako sharks in the South Atlantic indicate a high degree of uncertainty (ICCAT 2017). One model (Just Another Gibbs Sampler emulating the Bayesian production model) estimated that the stock was not overfished ($B_{2015}/B_{MSY}=1.69-1.75$) but that overfishing may be occurring ($F_{2015}/F_{MSY}=0.86-1.07$). Two runs from this model indicate a 0.3–1.4 percent probability of the stock being overfished and overfishing occurring, and a 29–47.4 percent probability of the stock not being overfished but

overfishing occurring, or, alternatively, the stock being overfished but overfishing not occurring, and a 52.3-69.6 percent probability of the stock not being overfished and overfishing not occurring (ICCAT 2017). The Just Another Bayesian Biomass Assessment (JABBA) model results indicated an implausible stock trajectory and were, therefore, not relied upon for management advice. The Catch-only Monte-Carlo method (CMSY) model estimates indicate that the stock could be overfished ($B_{2015}/B_{MSY} = 0.65$ to 1.12) and that overfishing is likely occurring $(F_{2015}/F_{MSY} = 1.02 \text{ to } 3.67)$. Considering catch scenarios C1 (catches starting in 1950 in the north and 1971 in the south, as reported in the March 2017 ICCAT shortfin make data preparatory meeting) and C2 (alternative estimated catch series based on ratios (method described by Coelho and Rosa 2017), starting in 1971), Catch-only Monte-Carlo method model estimates indicated a 23-89 percent probability of the stock being overfished and overfishing occurring, a 11-48 percent probability of the stock not being overfished but overfishing occurring, or alternatively, the stock being overfished but overfishing not occurring, and only a 0-29 percent probability of the stock not being overfished and overfishing not occurring. Generally, while CPUE exhibited an increasing trend over the last 15 years, both catches and effort increased contrary to the expectation that the population is expected to decline with increasing catch (FAO 2019). This inconsistency caused the ICCAT working group to consider the assessment highly uncertain, and they conducted no projections for the South Atlantic stock. Nevertheless, the combined assessment models found a 19 percent probability that the stock is overfished and is experiencing overfishing, a 48 percent probability of the stock not being overfished but overfishing occurring, or alternatively, the stock being overfished but overfishing not occurring, and a 36 percent probability that the stock is not being overfished or experiencing overfishing (ICCAT 2017). The assessment also notes that, despite uncertainty, in recent years the stock may have been at, or is already below, B_{MSY}, and fishing mortality is already exceeding F_{MSY}. Based on the uncertainty of the stock status, combined with the species' low productivity, the ICCAT working group concluded that catches should not increase above average catch for the previous 5 years, about 2,900 t (ICCAT 2017; FAO 2019). There is a significant

risk that the South Atlantic stock could follow a trend similar to that of the North Atlantic stock given that fishery development in the South Atlantic predictably follows that in the North, and that the biological characteristics of the stock are similar. The 2019 update to the stock assessment (ICCAT 2019) therefore reiterates the recommendation that, at a minimum, catch levels should not exceed the minimum catch in the last 5 years of the assessment (2,001 t with catch scenario C1).

In addition to the ICCAT stock assessment, standardized catch rates in South Atlantic longlines indicate steep declines in the average CPUE of shortfin mako shark between 1979-1997 and 2007-2012 (Barreto et al. 2016). However, the methodologies used in this study have several caveats and limitations, including the standardization analysis being applied individually to each of the time series and the use of different variables. Therefore, the results are not directly comparable between the different time periods and cannot be used to infer the total extent of decline over the entirety of the time series (FAO 2019).

Overall, despite high uncertainty in abundance and trends for the species in this region, the best available scientific and commercial data indicate that there is a 19 percent probability that the population is overfished and is experiencing overfishing, and in recent years the stock may have been at, or is already below, B_{MSY} and fishing mortality is already exceeding F_{MSY}.

North Pacific Ocean

The most comprehensive information on trends for shortfin make sharks in the North Pacific comes from the 2018 ISC Shark Working Group stock assessment, which found that the North Pacific stock was likely not in an overfished condition and was likely not experiencing overfishing between 1975 and 2016 (42 years) (ISC Shark Working Group 2018). This analysis used a Stock Synthesis model that incorporated sizeand age-specific biological parameters and utilized annual catch data from 18 fleets between 1975 and 2016, annual abundance indices from five fleets for the same period, and annual size composition data from 11 fleets between 1994 and 2016 (Kai 2021a). This assessment determined that the abundance of mature females was 860,200 in 2016, which was estimated to be 36 percent higher than the number of mature females at maximum sustainable yield (MSY) (ISC Shark Working Group 2018). Future projections indicated that spawning abundances were expected to increase

gradually over a 10-year period (2017–2026) if fishing mortality remains constant or is moderately decreased relative to 2013–2015 levels (ISC Shark Working Group 2018). Using results from the ISC stock assessment, historical decline in abundance (1975–1985 to 2006–2016) is estimated at 16.4 percent, and a recent increase (2006–2016) is estimated at 1.8 percent (CITES 2019).

The IUCN Red List Assessment for global shortfin make shark also used the ISC assessment to model the average trend in the North Pacific stock over three generation lengths (72 years) and indicated a median decline of 36.5 percent based on annual rates of decline of 0.6 percent from 1975–2016 (Rigby et al. 2019). A comprehensive comparison of the assessments by the ISC and the IUCN (Kai 2021a) describes JARA (applied by Rigby et al. 2019) as a useful tool in extinction risk assessments for data-poor pelagic sharks, but inappropriate for the relatively data-rich North Pacific shortfin make shark. The assessment by IUCN used only the mean annual trends in the population over the assessment period estimated from Stock Synthesis, and did not consider size or age structure of the population over recent decades. Kai (2021a) concludes that the results of the ISC's assessment of current and future status of North Pacific shortfin make shark are more robust and reliable than those of the IUCN, and finds a median decline of the population trajectory of 12.1 percent over three generation lengths with low uncertainty.

The ISC Shark Working Group's 2021 indicator-based analysis for shortfin mako sharks in the North Pacific used time series of catch, indices of relative abundance (CPUE), and lengthfrequency data from multiple fisheries over the time period 1957-2019 to monitor for potential changes in stock abundance since the 2018 benchmark assessment. Catch of shortfin mako shark in 2019 was the second highest value for the last decade, and the scaled CPUEs indicated a stable and slightly increasing trend in the four major fleets (U.S. Hawaii longline shallow-set, Taiwan longline large-scale, Japan research and training vessels, and Mexico observer for longline) (ISC Shark Working Group 2021). The Working Group concluded that there were no signs of major shifts in the tracked indicators that would suggest a revision to the current stock assessment schedule for shortfin make shark is necessary (ISC Shark Working Group 2021). The next stock assessment is scheduled for 2024.

Observer data from the Western and Central Pacific Fisheries Commission (WCPFC) indicate that longline catch rates of mako sharks in the North Pacific declined significantly by an average of 7 percent (95 percent confidence interval (CI): 3–11 percent) annually between 1995 and 2010 (Clarke et al. 2013). However, these data represent trends for both longfin and shortfin make sharks combined, and the performance of the standardization model was poorer than for other studied shark species, making the estimated trend less reliable. There were also variable size trends for make sharks in the North Pacific, with females showing significant increases in median length in one region (Clarke et al. 2013). In an updated indicator analysis using the same data, Rice et al. (2015) noted that the standardized CPUE trend looked relatively stable between 2000 and 2010, but no inference was possible for the last 4 years (2010-2014) due to data deficiencies in some years.

Kai *et al.* (2017) analyzed catch rates in the Japanese shallow-set longline fishery in the western and central North Pacific from 2006-2014, finding an increasing trend since 2008. However, fishery-independent logbook data collected from Japanese research and training vessels in the western and central North Pacific (mainly 0-40° N and 130° E-140° W) from 1992-2016 showed a decreasing catch rate since 2008 (Kai 2019). The opposing trends indicated by fishery-dependent and -independent data in this region may be due to factors such as differing areas of operation, differing gear types, underreporting by both data sources, and differing model structures applied to the data (Kai 2019). Additionally, standardized CPUE estimates from 2011-2019 in the Japanese longline fleet operating in the North Pacific Ocean showed a stable trend from 2011 to 2016, with a slight decline after 2016 (Kanaiwa et al. 2021). The authors note that observer coverage in the fleet is low (1.7-3.0 percent in certain areas) and that these results may not represent the overall trend for the North Pacific stock of shortfin mako shark (Kanaiwa et al.

Results from stock assessments and standardized CPUE trends from observer data are more comprehensive, robust, and reliable than trends from fishery logbook data. Therefore, we find that the best scientific and commercial information available indicates that shortfin make sharks in the North Pacific are neither overfished nor experiencing overfishing, and the population is likely stable and potentially increasing despite evidence

of historical decline and indications of recent decline in fishery-independent datasets.

South Pacific Ocean

In the South Pacific, longline catch rates reported to WCPFC did not indicate a significant trend in abundance of mako shark (shortfin and longfin combined) between 1995 and 2010 (Clarke et al. 2013). In an updated indicator analysis, standardized CPUEs for the make shark complex show a relatively stable trend in relative abundance, with low points in 2002 and 2014, though the 2014 point is based on relatively few data and should be interpreted with caution (Rice et al. 2015). In New Zealand waters, logbook and observer data from 1995-2013 analyzed by Francis et al. (2014) indicate that shortfin make sharks were not declining, and may have been increasing, over the period from 2005-2013. More recently, an analysis of the data did not result in statistically significant trend fits for two of the data series; those that were significant were increasing (Japanese South 2006-2015, Domestic North 2006-2013, and Observer Data 2004-2013) (FAO 2019). Trend analysis of modeled biomass indicates a median increase of 35.2 percent over three generation lengths based on estimated annual rates of increase of 0.5 percent from 1995-2013 (Rigby et al. 2019). In sum, the best scientific and commercial information available indicates that shortfin make sharks in the South Pacific have an increasing population trend.

Indian Ocean

Only preliminary stock assessments using data-limited assessment methods have been conducted for the shortfin mako shark in the Indian Ocean, with few other stock indicators available. Catch data are thought to be incomplete for several reasons: landings do not reflect the number of individuals finned and discarded at sea, shortfin make sharks are not sufficiently specified in catch data and are often aggregated with other species, shortfin make shark may be misidentified as longfin make shark, and recorded weight may often refer to processed weight rather than live weight (Bonhommeau et al. 2020). These factors were a significant consideration in our evaluation of the species. With these caveats in mind, a preliminary assessment by Brunel et al. (2018) was carried out based on CPUE estimates from Portuguese (2000-2016) and Spanish (2006–2016) swordfish and tuna longline fleets operating in the Indian Ocean Tuna Commission (IOTC) Convention area. Results from two

models (a Bayesian Schaefer-type production model and another model analyzing the trends of catches) indicate that the stock is experiencing overfishing ($F_{2015}/\bar{F}_{MSY} = 2.57$), but is not vet overfished (B₂₀₁₅/B_{MSY} close to one) (Brunel et al. 2018). However, there were considerable uncertainties in the estimates and conflicting trends in biomass between the two models used. Nonetheless, trajectories showed consistent trends toward both overfished and subject to overfishing status (Brunel et al. 2018). Using the results of the Schaefer model from Brunel et al. (2018), historical decline (1970-1980 to 2005-2015) was estimated at 26 percent, recent decline (2005 to 2015) was estimated at 18.8 percent, and future 10-year decline was projected at 41.6 percent from the historical baseline (1970–1980 to 2015– 2025) (CITES 2019). A trend analysis for modeled biomass in the Indian Ocean using Brunel et al.'s assessment indicates a median decline of 47.9 percent over three generation lengths based on annual rates of decline of 0.9 percent from 1971-2015 (Rigby et al.

A more recent preliminary assessment using updated catch and CPUE indices also indicates that the shortfin make shark in the Indian Ocean is experiencing overfishing but is not overfished (Bonhommeau et al. 2020). This assessment uses nominal catch of shortfin make shark as reported to the IOTC (1964-2018) and scaled CPUEs from Japan (1993-2018), Spain (2001-2018), Taiwan (2005-2018), and Portugal (2000–2018). Bonhommeau et al. (2020) used JABBA and CMSY models, both of which gave results that were generally consistent with the previous assessment: that the stock is currently undergoing overfishing and is not overfished.

In a separate study, Wu et al. (2021) analyzed standardized CPUE trends using observer records and logbook data from 2005-2018 for the Taiwanese longline fishery in the Indian Ocean, which was the second largest shortfin make shark-catching nation in the region in 2019. The standardized CPUEs indicate a gradual decrease between 2005 and 2007, followed by a sharp increase in 2008, a slow decline between 2008 and 2015, and another increase between 2015 and 2018 (Wu et al. 2021). However, Wu et al. (2021) note that the rapid increases in CPUEs between 2007 and 2008 and later between 2015 and 2017 may be unrealistic for the stock biomass of such a long-lived species, and suggest that the results may be due to increased reporting by skippers and observers.

Logbook data from Japanese longliners operating in the Indian Ocean from 1993–2018 indicate that abundance of shortfin mako shark decreased from 1993-2009, and increased slightly since then (Kai and Semba 2019). Standardized CPUE has risen after 2008 in Portuguese and Spanish longline fleets as well (Coelho et al. 2020; Ramos-Cartelle et al. 2020), although these data sets were included in the preliminary stock assessment conducted by Bonhommeau et al. (2020). In the Arabian Sea CPUE data suggest variable abundance and little evidence of significant population reduction (Jabado et al. 2017). Fishing pressure in this region is high, and because the species has high susceptibility to pelagic fisheries, Jabado et al. (2017) estimated that over the past 3 generations the population has declined 20-30 percent, with future declines expected over the next 3 generations. Results from these studies may reflect partial stock status in the Indian Ocean, but may not have sufficient spatial coverage to be indicative of the entire stock status.

In sum, the best available scientific and commercial information indicates that shortfin make shark population in the Indian Ocean is experiencing overfishing but is not yet overfished, and recent increasing CPUE trends are indicated in Spanish, Portuguese, and Taiwanese longline fleets. Catch data have the potential to be substantially underestimated and the recent increases in CPUE from these fleets may not reflect trends in abundance.

Summary

Overall, while abundance estimates for the shortfin make shark are not available for all regions, the stock assessments available for the North Atlantic and North Pacific Oceans indicate current numbers of about one million and eight million individuals, respectively (FAO 2019). These estimates were generated by the FAO Expert Advisory Panel, which extracted these numbers using the age-structured assessments conducted by ICCAT (2017) and the ICS Shark Working Group (2018). Rigby et al. (2019) conducted a trend analysis of shortfin make shark abundance indices using the 2017 ICCAT stock assessment in the Atlantic, the 2018 ISC Shark Working Group stock assessment in the North Pacific, a preliminary stock assessment for the Indian Ocean (Brunel et al. 2018), and a CPUE indicator analysis from New Zealand for the South Pacific (Francis *et* al. 2014). Due to the unreliable stock assessment in the South Atlantic, Rigby et al. (2019) considered the North Atlantic stock assessment to be

representative of the South Atlantic for the trend analysis. However, this may have inaccurately represented the extent of decline in the South Atlantic for reasons described above. This assessment estimates the overall median population reduction for the global shortfin make shark population at 46.6 percent, with the highest probability of 50–79 percent reduction over three generation lengths (72-75 years) (Rigby et al. 2019), although the JARA framework used by Rigby et al. has been described as inappropriate for this species as it only uses mean annual trends in the population over the assessment period and does not consider size or age structure of the population over recent decades (Kai 2021a).

Population decline has been indicated in the North Atlantic with high certainty, and abundance is likely to continue declining until at least 2035 even in the absence of fishing mortality (ICCAT 2019). In the North Pacific, while there is evidence of historical decline, recent assessments indicate that the stock is neither overfished nor experiencing overfishing, and the population is likely stable or potentially increasing (ISC Shark Working Group 2018). Although a stock assessment has not been completed for shortfin make sharks in the South Pacific, the best available scientific and commercial data and analyses indicate an increasing population trend (Francis et al. 2014; Rigby et al. 2019). Abundance of the shortfin mako shark in the South Atlantic and Indian Oceans is not as clear, given significant uncertainties in the data available from these regions. The most recent stock assessments of shortfin mako sharks in the South Atlantic has a high degree of uncertainty, and indicate a combined 19 percent probability that the stock is overfished and experiencing overfishing (ICCAT 2017). Preliminary assessments in the Indian Ocean indicate that the population is experiencing overfishing but is not yet overfished (Brunel et al. 2018; Bonhommeau et al. 2020).

Extinction Risk Analysis

In evaluating the level of risk faced by a species and deciding whether the species is threatened or endangered, we must consider all relevant data and are required under the ESA to base our conclusions on the best scientific and commercial data available. In evaluating and interpreting the best available data we also apply professional judgment. We evaluate both the viability of the species based on its demographic characteristics (abundance, productivity, spatial distribution, and

diversity; see McElhany *et al.* (2000)), and the threats to the species as specified in ESA section 4(a)(1)(A)–(E).

Methods

This section discusses the methods used to evaluate threats and the overall extinction risk to the shortfin mako shark. For purposes of the risk assessment, an ERA Team comprising biologists and shark experts was convened to review the best available information on the species and evaluate the overall risk of extinction facing the shortfin mako shark, now and in the foreseeable future.

According to regulations implementing section 4 of the ESA that were in place during the ERA Team's deliberations, which was consistent with our practice since 2009 in accordance with a legal opinion of the Solicitor of the United States Department of the Interior, "The Meaning of 'Foreseeable Future' in section 3(20) of the Endangered Species Act" (M-37021, Jan. 16, 2009; referred to herein as "the 2009 M-Opinion"), the foreseeable future extends only so far into the future as we can reasonably determine that both the future threats and the species' responses to those threats are likely. See 50 CFR 424.11(d). Under our longstanding practice we describe the foreseeable future on a case-by-case basis, using the best available data and taking into account considerations such as the species' lifehistory characteristics, threat-projection timeframes, and environmental variability. In addition, because a species may be susceptible to a variety of threats for which different data are available, or which operate across different time scales, the foreseeable future may not necessarily be reducible to a particular number of years and may not be defined the same way for each threat. Although the regulations were vacated and remanded without a decision on the merits on July 5, 2022, by the United States District Court for the Northern District of California, and that order has been temporarily stayed as of September 21, 2022, whether or not those regulations remain in place does not affect our understanding or application of the "foreseeable future." The 2019 regulations merely codified the approach of our longstanding interpretation of this term in use prior to the issuance of these regulations (see 84 FR 45020, August 27, 2019), and the court did not make any findings on the merits that would call this approach into question. Thus, with or without the 2019 regulations, we would continue to apply an approach to the foreseeable future rooted in the 2009 M-Opinion.

In determining an appropriate foreseeable future timeframe for the shortfin mako shark, the ERA Team first considered the species' life history. The species matures late in life, with females estimated to mature at an age of 15-21 years and males at 6-9 years of age (Bishop et al. 2006; Natanson et al. 2006; Šemba et al. 2009; Groeneveld et al. 2014). The species has high longevity of at least 28-32 years (Bishop et al. 2006; Natanson et al. 2006) and exhibits relatively slow growth rates and low productivity (Cortés et al. 2015). The ERA Team also considered generation time for the shortfin make shark, which is defined as the average interval between the birth of an individual and the birth of its offspring, and has been estimated at 25 years (Cortés et al. 2015). Given the life history characteristics of the shortfin make shark, the ERA Team concluded that it would likely take several decades for any conservation management actions to be realized and reflected in population abundance indices.

As the main threats to the species are overutilization in commercial fisheries and the inadequacy of regulatory measures that manage these fisheries (see Summary and Analysis of Section 4(a)(1) Factors below), the ERA Team then considered the time period over which they could reasonably predict the likely impact of these threats on the biological status of the species. The ERA Team took available projections for shortfin mako shark abundance into consideration: the 2019 ICCAT update to the stock assessment for the North Atlantic carried out projections over 2 generation lengths, or 50 years; the ISC Shark Working Group's 2018 stock assessment for North Pacific shortfin mako sharks used 10-year projections; and the IUCN Red List Assessment carried out projections based on available data to achieve a 3 generation length time frame using JARA.

In examining these projections and their respective confidence intervals, the ERA Team noted that uncertainty increased substantially after about one generation length in all cases across multiple regions of the species' range. The ERA Team noted that in the IUCN JARA projections conducted for shortfin mako sharks by region, uncertainty (i.e., the difference between the median and confidence intervals) increased to 50 percent by 2030 for the South Pacific population (about 18 years projected), and 40 percent by 2040 for the Indian and North Pacific populations (about 25 years projected). Additionally, the ERA Team noted that ICCAT's report of the 2019 shortfin mako shark stock assessment update meeting emphasizes

that the Kobe II Strategy Matrix (K2SM) used to provide scientific advice for the North Atlantic stock does not capture all uncertainties associated with the fishery and the species' biology. Specifically, ICCAT's SCRS stated that "the length of the projection period (50 years) requested by the Commission significantly increases the uncertainty of the results. Therefore, the Group advised that the results of the K2SM should be interpreted with caution,' (ICCAT 2019). As a result of this statement, the ERA Team considered the 50-year projection to have questionable scientific merit, with estimates over that time frame only provided because the Commission requested them. Given the concerns about uncertainty that were repeatedly highlighted by the SCRS (ICCAT 2019), the ERA Team concluded that the 50-year period was not an appropriate time period for the foreseeable future.

In addition to uncertainty in projected abundance trends, the ERA Team discussed the uncertainty associated with future management measures and fishing behavior across regions. ICCAT is currently the only major Regional Fishery Management Organization (RFMO) with management measures specific to shortfin make sharks, and recently adopted a two-year retention ban for the species in the North Atlantic. The conservation benefit of this measure is uncertain, however, as it does not require fishermen to modify gear or fishing behavior that would reduce at-vessel or post-release mortality of the species. Further, management of the species after this two-year ban expires is unknown. Some of the top shortfin make shark-catching nations in this region (Spain, Portugal, and Morocco) have very recently announced unilateral retention prohibitions for North Atlantic shortfin mako shark, although the effect these bans will have on the species is again unknown, even if they ultimately are well implemented. Although projections carried out in 2019 by ICCAT's SCRS indicate that the North Atlantic stock will continue declining until approximately 2035 regardless of fishing mortality, the effect on stock status beyond this varies greatly with fishing mortality levels. Beyond the North Atlantic and North Pacific (where fishing data is also considered robust), fishing harvest and, especially, at-vessel and post-release mortality data are less thoroughly documented, introducing considerable uncertainty in projections of fishery impacts past a few decades.

After considering the best available scientific and commercial information on the shortfin make shark's life history,

projected abundance trends, and current and future management measures and fishing behaviors, the ERA Team concluded that a biologically reasonable foreseeable future timeframe would be 25 years, or one generation length, for the shortfin make shark. Because the main threats to the species are overutilization in commercial fisheries and the inadequacy of existing regulatory mechanisms to prevent overutilization in these fisheries, the ERA Team found that this timeframe would allow for reliable predictions regarding the likely impact of these threats on the future biological status of the species.

While we conclude that the ERA Team assembled the best scientific and commercial information, it is the role of the agency rather than the team to determine the appropriate application of the agency's interpretations of key statutory terms and of agency policy to the factual record, and to ultimately determine the species' listing status under the ESA. Based on the best available scientific and commercial information, we disagree with the ERA Team's conclusion that the foreseeable future extends only 25 years, or one generation length, and have determined that application of a 50-year time frame is more appropriate in this case generally, though for some individual threats our ability to predict the specific trends and the species' responses is less robust than for others. We agree that fisheries mortality and inadequate regulatory mechanisms to address this threat are, and will continue to be, the main threats to the species. While we also agree with the ERA Team's characterization of the shortfin make shark's life history, we find this information to indicate that it would take more than one generation length for effects of conservation actions to be reflected in abundance indices. During peer review of the Status Review Report, reviewers noted that changes in threats and conservation measures for shortfin mako sharks might take decades to become visible in the mature population, and all three reviewers were of the opinion that a longer time horizon would be appropriate. We find that the ERA Team unnecessarily limited the length of the foreseeable future by relying on statistical confidence levels for projected population trends. The 2009 M-Opinion, which for over a decade has provided the basis for NMFS's interpretation of this term, states that "the foreseeable future for a given species is not limited to the length of time into the future for which a species' status can be quantitatively

modeled or predicted within predetermined limits of statistical confidence; however, uncertainties of any modeling efforts should be considered and documented.' Although, as the ERA Team noted, uncertainty in abundance projections increases with the length of projections, we have determined that we can use available projections, our knowledge of the species' life history, and predicted levels of fishing mortality to inform what is likely to be the status of the species in a given region over a longer timeframe. Also, although changes in threats (i.e., fisheries removals) would be observable over a 25-year period, we do not find that this time period is sufficient to measure and understand the population-level response to these changes, which would only be observable over a longer time period given the species' late age-at-maturity (this was also noted by a reviewer during the peer review process of the Status Review Report). A 50-year timeframe would encompass the duration over which changes in productivity would be expected to occur and be measurable while also taking into account the considerable uncertainty in future management measures and population trends as described by the ERA Team. To conclude, we find that our knowledge of the species' life history and of the fisheries impacting the species allow us to reasonably determine the likely threats facing the species (overutilization for commercial purposes and the related inadequacy of existing regulatory mechanisms) and the species' likely response to these threats (reflected in abundance trends and other demographic factors) over approximately 50 years, or two generation lengths. We therefore consider the foreseeable future to extend 50 years (two generation lengths) rather than 25 years as determined by the ERA

The ability to measure or document risk factors to a marine species is often limited, and quantitative estimates of abundance and life history information are often lacking altogether. Therefore, in assessing extinction risk of a species with limited data available from certain regions, it is important to include both qualitative and quantitative information. In assessing extinction risk to the shortfin mako shark, the ERA Team considered the demographic viability factors developed by McElhany et al. (2000) and the risk matrix approach developed by Wainwright and Kope (1999) to organize and summarize extinction risk considerations. The

approach of considering demographic risk factors to help frame the consideration of extinction risk has been used in many of our status reviews (which can be accessed online at http:// www.nmfs.noaa.gov/pr/species). In this approach, the collective condition of individual populations is considered at the species level according to four demographic viability factors: abundance, growth rate/productivity, spatial structure/connectivity, and diversity. These viability factors reflect concepts that are well-founded in conservation biology and that individually and collectively provide strong indicators of extinction risk. To some extent these factors reflect the impacts that the operative threats have already had or are having on the species.

Using these concepts, the ERA Team evaluated demographic risks by assigning a risk score to each of the four demographic risk factors. The contribution of each demographic factor to extinction risk was scored according to the following scale: 0—unknown risk, 1—low risk, 2—moderate risk, and 3 high risk. Detailed definitions of the risk scores can be found in the Status Review Report. The scores were then tallied and summarized for each demographic factor. The ERA Team discussed the range of perspectives for each of the factors and the supporting data upon which they were based. ERA Team members were then given the opportunity to revise scores after the discussion if they felt their initial analysis had missed any pertinent data discussed in the group setting.

The ERA Team also performed a threats assessment for the shortfin make shark by evaluating each threat in terms of its contribution to the extinction risk of the species. The contribution of each threat to the species' extinction risk was scored on the following scale: 0unknown risk, 1—low risk, 2—moderate risk, and 3-high risk. The scores were then tallied and summarized for each threat, and the ERA Team again discussed the range of perspectives before providing final scores. As part of the threats assessment, the ERA Team considered the synergistic and combined effects of the threats acting together as well as individually. It should be emphasized that the scoring exercise for both demographic risks and threats was simply a tool to help the ERA Team members organize the information and assist in their thought processes for determining the overall risk of extinction for the shortfin mako shark, and is a common and wellaccepted feature of our species assessments.

Guided by the results from the demographic risk analysis and the threats assessment, the ERA Team members were asked to use their informed professional judgment to make an overall extinction risk determination for the shortfin make shark. For this analysis, the ERA Team considered three levels of extinction risk: 1-low risk, 2-moderate risk, and 3-high risk. Detailed definitions of these risk levels are as follows: 1 = Low risk: A species is at low risk of extinction if it is not at a moderate or high level of extinction risk (see "Moderate risk" and "High risk" below). A species may be at a low risk of extinction if it is not facing threats that result in declining trends in abundance, productivity, spatial structure, or diversity. A species at low risk of extinction is likely to show stable or increasing trends in abundance and productivity with connected, diverse populations; 2 = Moderate risk: A species is at moderate risk of extinction if it is on a trajectory that puts it at a high level of extinction risk in the foreseeable future (50 years in this case) (see description of "High risk"). A species may be at moderate risk of extinction due to projected threats or declining trends in abundance, productivity, spatial structure, or diversity; 3 = High risk: A species with a high risk of extinction is at or near a level of abundance, productivity, spatial structure, and/or diversity that places its continued persistence in question. The demographics of a species at such a high level of risk may be highly uncertain and strongly influenced by stochastic or depensatory processes. Similarly, a species may be at high risk of extinction if it faces clear and present threats (e.g., confinement to a small geographic area; imminent destruction, modification, or curtailment of its habitat; or disease epidemic) that are likely to create present and substantial demographic

The ERA Team adopted the "likelihood point" method for ranking the overall risk of extinction to allow individuals to express uncertainty. Following this method, each ERA Team member distributed 10 "likelihood points" across the three extinction risk levels, representing the likelihood that the species falls into each risk category. Each Team member had the ability to cast points in more than one category to account for uncertainty, and the points that each Team member allocated across the categories summed to 10. This method has been used in previous NMFS status reviews (e.g., oceanic whitetip shark, Pacific salmon, Southern Resident killer whale, Puget

Sound rockfish, Pacific herring, and black abalone) to structure the ERA Team's thinking and express levels of uncertainty when assigning risk categories. After scores were provided, the ERA Team discussed the range of perspectives and the supporting data on which scores were based, and members were given the opportunity to revise scores if desired after the discussion. Likelihood points were then summed by extinction risk category. Other descriptive statistics, such as mean, variance, and standard deviation, were not calculated, as the ERA Team concluded that these metrics would add artificial precision to the results.

Finally, consistent with the appropriately limited role of the Team, the ERA Team did not make ultimate recommendations as to whether the species should be listed as threatened or endangered. Rather, the ERA Team drew scientific conclusions about the overall risk of extinction faced by the shortfin mako shark under present conditions and in the foreseeable future based on an evaluation of the species' demographic risks and assessment of threats.

Because we determined to adopt a different period of years as the "foreseeable future" for the shortfin make shark after the ERA Team's work concluded, we also present our own assessment of extinction risk over the foreseeable future (50 years or two generation lengths) in a later section of this document alongside the ERA Team's results.

Demographic Risk Analysis

Abundance

The ERA Team assessed available abundance and trend information by region, including formal stock assessments, preliminary stock assessments using data-limited assessment methods, and standardized CPUE trends. There are no global abundance estimates available; however, using the formal stock assessments available for the North Atlantic and North Pacific, current abundance has been estimated at one million and eight million individuals, respectively (FAO 2019). Using the regional rates of change weighted by an area-based estimate of the size of each region as a proportion of the species' global distribution, the IUCN Red List assessment estimated global decline at 46.6 percent over three generation lengths, with the particular years covered varying by region (Rigby et al. 2019). Although historical declines of varying degrees are evident across all oceans, current trends are mixed.

As discussed previously, the most recent stock assessment for shortfin mako shark in the North Atlantic indicates a combined 90 percent probability that the stock is in an overfished state and is experiencing overfishing (ICCAT 2017). The agestructured stock assessment model estimates historical declines in SSF from 1950 (unfished condition) to 2015 at 50 percent, and recent declines (from 2006-2015) at 32 percent (ICCAT 2017, FAO 2019). All nine assessment model runs were consistent, and together indicated that shortfin make sharks in the North Atlantic have experienced historical declines (1950-2015) in total biomass of 47-60 percent, and recent declines (2006-2015) in total biomass of 23-32 percent (ICCAT 2017, FAO 2019). The 2019 update to the stock assessment projects that even with a zero TAC, there is a 53 percent probability that the North Atlantic stock will be rebuilt and not experiencing overfishing by 2045, and that regardless of TAC (in this case, TAC refers to all sources of mortality and is not limited to landings), the stock will continue declining until 2035 (ICCAT 2019). Overall, the ERA Team agreed that the findings from the stock assessment and projections were concerning. The ERA Team discussed how to appropriately interpret the stock assessment's focus on being rebuilt (SSF > SSF_{MSY}) and without overfishing (F < F_{MSY}) in the context of assessing extinction risk. As discussed previously in Abundance and Trends, while the fisheries management goal of rebuilding an overfished stock relates to achieving biomass levels that will allow for production of MSY, this can be significantly above the biomass levels necessary to ensure that a species is not in danger of extinction. While it will likely take decades for the stock to meet these fisheries management criteria (rebuilt and without overfishing), this does not indicate that the stock is at risk of becoming extirpated now or over the foreseeable future. Additionally, the ERA Team weighed the potential effects of the recent two-year North Atlantic shortfin mako shark retention prohibition on fishing mortality and abundance (ICCAT Recommendation 21-09, discussed in *Inadequacy of* Existing Regulatory Mechanisms below, which entered into force on June 17, 2022). As data for each fishing year is not reported until the following calendar year, the effect of this measure on fishing mortality will not be easily assessed until 2024 when the landings and discard data from 2023 can be analyzed. As noted above, the low productivity and slow population

growth of shortfin mako shark may also mean that measurable impacts of this measure on abundance do not manifest for several years, when a new cohort enters the fishery. The Team concluded that there was significant uncertainty concerning both the effect of the measure and the future management of the stock after the two-year time period, and therefore did not significantly rely on any potential effect of the measure when drawing conclusions about the stock's abundance or trends.

We agree with the ERA Team's assessment of abundance and related considerations in the North Atlantic. We also recognize that without a substantial reduction in total fishing mortality (annual TAC of 500 t or less), it is unlikely that the stock will be rebuilt by 2070 (ICCAT 2019). Even if the spawning stock is not considered rebuilt by the stock assessment metric (SSF > SSF_{MSY}), this does not necessarily mean that the stock will be in danger of being extirpated. However, given that fishing mortality is still high in this region (1,709 t in 2020) compared to even the greatest assessed TAC level (1,100 t), this level of removal will lead to continued declines. Unless aggressive management measures effectively reduce fishing mortality in this region, declines will likely continue throughout the foreseeable future (50 years). ICCAT has a demonstrated track record of taking multilateral actions to address data gaps and to respond to indications of declining stock status (see previous ICCAT measures specific to the stock in Inadequacy of Existing Regulatory Mechanisms below). The two-year retention prohibition adopted by ICCAT in 2021 is the most recent step that has been taken to conserve and manage this stock in line with the ICCAT Convention. ICCAT's track record would indicate that similar or additional measures are likely to be continued or taken, as needed, to ensure ICCAT's objectives of ending overfishing and rebuilding the stock to levels that support MSY are met. Recommendation 21–09 calls for the Commission to review the measure no later than the annual meeting in 2024 to consider additional measures to reduce total fishing mortality. Overall, we conclude that the best available scientific and commercial data indicate that the stock is overfished and experiencing overfishing, has experienced an estimated 50 percent decline in SSF from 1950 to 2015, and will continue decreasing until 2035 regardless of TAC.

The 2017 stock assessment for shortfin make sharks in the South Atlantic indicated a high degree of uncertainty. The combined assessment models found a 19 percent probability that the population is overfished and is experiencing overfishing (ICCAT 2017). The authors concluded that despite high uncertainty, in recent years the South Atlantic stock may have been at, or already below, B_{MSY} and fishing mortality is likely exceeding F_{MSY} (ICCAT 2017). Projections for the stock were not completed in 2019 due to high uncertainty. The ERA Team agreed that the best available scientific and commercial data indicate some degree of historical and ongoing population decline, but was unable to draw conclusions about the degree of decline due to the highly uncertain results of the 2017 stock assessment. We agree with the ERA Team's assessment of abundance in the South Atlantic.

The most comprehensive information on trends for shortfin make sharks in the North Pacific comes from the 2018 ISC Shark Working Group stock assessment, which found that the North Pacific stock was likely not in an overfished condition and was likely not experiencing overfishing between 1975 and 2016 (42 years) (ISC Shark Working Group 2018). This assessment determined that the abundance of mature females was 860,200 in 2016, which was estimated to be 36 percent higher than the number of mature females at MSY (ISC Shark Working Group 2018). Future projections indicated that spawning abundance is expected to increase gradually over a 10-year period (2017-2026) if fishing mortality remains constant or is moderately decreased relative to 2013-2015 levels (ISC Shark Working Group 2018). Using results from the ISC stock assessment, historical decline in abundance (1975–1985 to 2006–2016) is estimated at 16.4 percent, and a recent increase (2006-2016) is estimated at 1.8 percent (CITES 2019). While the IUCN used the ISC assessment to model the average trend in the North Pacific stock over three generation lengths (72 years), resulting in a median decline of 36.5 percent (Rigby et al. 2019), Kai (2021a) found a median decline of the population trajectory of 12.1 percent over three generation lengths with low uncertainty. The ERA Team concluded that despite evidence of historical decline, the best available scientific and commercial data indicate that shortfin mako sharks in the North Pacific are neither overfished nor experiencing overfishing, and the population is likely stable and potentially increasing. We agree with the ERA Team's conclusion.

Although a stock assessment is not available for shortfin make sharks in the South Pacific, available information

indicates that the population is increasing. Standardized CPUEs for the mako shark complex (*i.e.*, both shortfin and longfin mako shark) show a relatively stable trend in relative abundance, with low points in 2002 and 2014, though the 2014 point is based on relatively few data and should be interpreted with caution (Rice et al. 2015). In New Zealand waters, logbook and observer data from 1995-2013 analyzed by Francis et al. (2014) indicate that shortfin make sharks were not declining, and may be increasing, over the period from 2005-2013. More recently, trend estimations using data from these two studies (Francis et al. 2014 and Rice et al. 2015) did not result in statistically significant trend fits for two of the data series; those that were significant were increasing (Japanese South 2006-2015, Domestic North 2006-2013, and Observer Data 2004-2013) (FAO 2019). Trend analysis of modeled biomass indicates a median increase of 35.2 percent over three generation lengths (Rigby et al. 2019). In sum, the ERA Team agreed that the best available scientific and commercial data for shortfin make sharks in the South Pacific indicate an increasing population trend, and we agree with the ERA Team's conclusion.

Finally, in the Indian Ocean, preliminary stock assessments using data-limited assessment methods are available for shortfin make sharks and indicate that the stock is experiencing overfishing, but is not yet overfished (Brunel et al. 2018; Bonhommeau et al. 2020). This means that while the stock is subjected to a level of fishing mortality that jeopardizes the stock's ability to produce MSY, biomass levels are still high enough that the stock is able to produce MSY on a continuing basis. Both preliminary assessments are considered highly uncertain due to limitations in catch data. Using the results of the Schaefer model from Brunel et al. (2018), historical decline (1970-1980 to 2005-2015) was estimated at 26 percent, recent decline (2005 to 2015) was estimated at 18.8 percent, and future 10-year decline was projected at 41.6 percent from the historic baseline (1970-1980 to 2015-2025) (CITES 2019). A trend analysis for modeled biomass in the Indian Ocean using Brunel et al.'s assessment indicates a median decline of 47.9 percent over three generation lengths (Rigby et al. 2019). Recent increases in CPUE trends are indicated in Spanish, Portuguese, and Taiwanese longline fleets (Coelho et al. 2020; Ramos-Cartelle et al. 2020; Wu et al. 2021), though it should be noted that these

datasets were included in the assessment by Bonhommeau *et al.* (2020). Overall, the ERA Team concluded that the best available scientific and commercial data indicate some level of historical population decline and indicate that shortfin mako sharks are currently experiencing overfishing in this region. We agree with the ERA Team's conclusion.

The ERA Team considered the risk associated with abundance of the global species using the best available scientific and commercial information, summarized above. Reported landings represent a substantial underestimate of mortality resulting from fisheries interactions because they do not fully account for mortalities that result from fisheries interactions, including sharks that are discarded dead, finned, or that experience post-release mortality, and therefore there is some level of uncertainty in all available stock assessments and abundance indices, particularly so in the South Atlantic and Indian Oceans, However, stock assessments in the North Atlantic and North Pacific were considered robust by the ERA Team. Some degree of historical decline is indicated in all ocean basins, and population declines are ongoing in the North Atlantic. In the South Pacific, there are no available stock assessments, so the positive trends indicated here are based on available studies with limited geographic scope. Overall, there is no indication that global abundance has declined to the point that reproductive success of the species has declined or inbreeding has resulted, nor is there evidence of other depensatory processes associated with small populations. All ERA Team members agreed that the best available scientific and commercial information indicates that the species' abundance does not put it at risk of extinction currently. Several ERA Team members were of the opinion that declining abundance trends would likely contribute to the species' risk of extinction in the foreseeable future as they defined it; however, the majority of ERA Team members concluded that global abundance trends are unlikely to contribute significantly to the species risk of extinction currently or in the foreseeable future as they defined it. We agree that this factor is not contributing significantly to the species' risk of extinction now.

Over the foreseeable future of 50 years that we have determined is more appropriate to apply for this species, we find that the best available scientific and commercial data indicate that the abundance factor is unlikely to significantly contribute to the species'

extinction risk. The shortfin make shark population in the Pacific Ocean basin (a major segment of the global population) is likely to be stable and/or potentially increasing over this time period. Despite historical levels of decline (estimated at 47–60 percent reduction in total biomass) and likely continued decreases in the North Atlantic until at least 2035 (there is the potential for the population to begin rebuilding after this time with appropriate reduction of fishing mortality through management measures), as well as potential continuing population decreases of unknown degrees in the Indian and South Atlantic Oceans, we conclude that the best available scientific and commercial information indicates that global population abundance will not likely decline to the point that will put the species at risk of extinction over this timeframe.

Productivity

The shortfin make shark exhibits high longevity (at least 28-32 years; Natanson et al. 2006; Dono et al. 2015), slow growth rates, late age at maturity (6-9 for males and 15-21 years for females; Natanson et al. 2006; Semba et al. 2009), long gestation (9-25 months; Mollet et al. 2000; Duffy and Francis 2001; Joung and Hsu 2005; Semba et al. 2011), and long reproductive cycles (3 years; Mollet et al. 2000; Joung and Hsu 2005). Cortés (2016) determined that the intrinsic rate of population increase (r_{max}) for Atlantic shortfin make sharks ranges from $0.036-0.134 \text{ yr}^{-1}$. This was among the lowest values calculated from 65 populations and species of sharks. The ERA Team therefore concluded that the productivity of the species is quite low. The species also exhibits low natural mortality (0.075-0.244 yr⁻¹; Cortés 2016) and a long generation time (25 years; Cortés et al. 2015). Together, the species' life history characteristics indicate that it is highly susceptible to depletion from exploitation or other high-intensity sources of mortality, and will recover slowly from declines brought on by such stressors. The ERA Team was largely in agreement that although this factor doesn't constitute a risk of extinction for the species currently, this factor would likely contribute significantly to the species' risk of extinction in the foreseeable future as they defined it, especially if exacerbated by impacts of fishing mortality and resulting declines in abundance. We agree that this factor is not contributing significantly to the species' risk of extinction now. Similarly, we find that the best available scientific and commercial data indicates that the

shortfin mako shark's low productivity will likely contribute significantly to the species' extinction risk over the foreseeable future of 50 years that we have determined is more appropriate to apply for this species.

Spatial Structure/Connectivity

Shortfin make sharks are globally distributed across all temperate and tropical ocean waters and utilize numerous habitat types including open ocean, continental shelf, shelf edge, and shelf slope habitats (Rogers et al. 2015b; Corrigan et al. 2018; Francis et al. 2019; Rigby et al. 2019; Santos et al. 2020; Gibson et al. 2021). This highly migratory species is capable of undertaking movements of several thousand kilometers (Kohler and Turner 2019; Francis et al. 2019), and is able to make vertical migrations in the water column to several hundred meters depth (Santos et al. 2021). As a red muscle endotherm, the species is able to regulate its body temperature, allowing it to tolerate a broad range of water temperatures (Watanabe et al. 2015). Connectivity among ocean basins has been demonstrated by several genetic studies. Taken together, results of available genetic analyses suggest that female shortfin mako sharks exhibit fidelity to ocean basins, while males readily move across the world's oceans and mate with females from various basins, thereby homogenizing genetic variability (Heist et al. 1996; Schrey and Heist 2003; Taguchi et al. 2011; Corrigan et al. 2018). The ERA Team unanimously agreed that, based on this information, this demographic factor is not likely to contribute significantly to the species' risk of extinction now or in the foreseeable future as they defined it. We agree that this factor is not contributing significantly to the species' risk of extinction now. Over the foreseeable future of 50 years that we have determined is more appropriate to apply for this species, we also find that this demographic factor is not likely to significantly contribute to the shortfin mako shark's risk of extinction because this factor is not currently negatively affecting the species' status and the best available scientific and commercial data suggests no basis to predict that this factor will change over the extended time horizon.

Diversity

In its consideration of the degree to which diversity (or lack thereof) might contribute to the extinction risk of the shortfin make shark, the ERA Team evaluated available information on genetic diversity as well as diversity of distribution and ecology. Available

genetic studies do not indicate that the species has experienced a significant loss of diversity that would contribute to extinction risk. In fact, haplotype diversity has been found to be high in several studies: 0.755 by Heist et al. (1996), 0.92 by Taguchi et al. (2011), and 0.894 by Corrigan et al. (2018). Nucleotide diversity has been found to be lower: 0.347 by Heist et al. (1996), 0.007 by Taguchi et al. (2011), and 0.004 by Corrigan et al. (2018). Genetic studies indicate a globally panmictic population, meaning that there is sufficient movement of shortfin mako sharks, and therefore gene flow, to reduce genetic differentiation among regions (Heist et al. 1996; Schrey and Heist 2003; Taguchi et al. 2011; Corrigan et al. 2018). We found no evidence that gene flow, migration, or dispersal has been reduced. The species occurs across a variety of habitats and regions (Rogers et al. 2015b; Rigby et al. 2019; Santos et al. 2020), and is able to consume a diversity of prey (Stillwell and Kohler 1982; Cortés 1999; Maia et al. 2006; Gorni et al. 2012); these characteristics protect against catastrophic events that may impact a certain region or prey species. For these reasons, the ERA Team unanimously agreed that it is not likely that this factor significantly contributes to the species risk of extinction now or in the foreseeable future as they defined it. We agree that this factor is not contributing significantly to the species' risk of extinction now. Similarly, over the foreseeable future of 50 years that we have determined is more appropriate to apply for this species, we also find that this demographic factor is not likely to significantly contribute to the shortfin mako shark's risk of extinction because this factor is not currently negatively affecting the species' status and the best available scientific and commercial data suggests there is no basis to predict that this factor will change over the extended time horizon.

Summary and Analysis of Section 4(a)(1) Factors

As described above, section 4(a)(1) of the ESA and NMFS' implementing regulations (50 CFR 424.11(c)) state that we must determine whether a species is endangered or threatened because of any one or a combination of the following factors: the present or threatened destruction, modification, or curtailment of its habitat or range; overutilization for commercial, recreational, scientific, or educational purposes; disease or predation; the inadequacy of existing regulatory mechanisms; or other natural or manmade factors affecting its continued

existence. The ERA Team assembled the best available scientific and commercial data and evaluated whether and the extent to which each of the foregoing factors contributed to the overall extinction risk of the global shortfin mako shark population. We summarize information regarding each of these threats below according to the factors specified in section 4(a)(1) of the ESA.

The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

The shortfin make shark is a highly migratory, pelagic species that spends time in a variety of open ocean and nearshore habitat types. The species is globally distributed from about 50° N (up to 60° N in the northeast Atlantic) to 50° S. While distribution is influenced by environmental variables including water temperature, prey distribution, and DO concentration, the shortfin mako shark is able to tolerate a broad thermal range and use a wide variety of prey resources. The ERA Team agreed that because shortfin make sharks have a high adaptive capacity and do not rely on a single habitat or prey type, they are able to modify their distributional range to remain in an environment conducive to their physiological and ecological needs. Additionally, there is no evidence that range contractions have occurred, or that destruction or modification of their habitat on a global scale has occurred to such a point that it has impacted the status of the species. Therefore, the ERA Team concluded that the best available scientific and commercial information indicates that loss and/or degradation of habitat are not likely to be contributing significantly to the extinction risk of the shortfin make shark now or in the foreseeable future as they defined it. We agree that this factor is not contributing significantly to the species' risk of extinction now. Because the contribution of habitat destruction, modification or curtailment to extinction risk is not likely to change from 25 to 50 years, we also find that this factor will not contribute significantly to extinction risk over the foreseeable future of 50 years that we have determined is more appropriate to apply for this species.

An analysis of potential threats posed by pollutants and environmental contaminants is carried out in *Other Natural or Manmade Factors Affecting its Continued Existence*, below, because this potential threat affects more than just the habitat or range of the species. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

The best available information indicates that the primary threat facing the shortfin make shark is overutilization in fisheries. The majority of the catch is taken incidentally in commercial fisheries throughout the species' range, and the species is often opportunistically retained due to the high value of its meat and fins (Camhi et al. 2008; Dent and Clarke 2015). The species is targeted in semi-industrial and artisanal fisheries in the Indian and Pacific Oceans, and as a sportfish in several recreational fisheries, though recreational fisheries are thought to have minimal contribution to the species' overutilization in comparison to effects from commercial fisheries.

Global reported catches of shortfin mako shark have risen substantially since 1980. According to the Food and Agriculture Organization of the United Nations (FAO) global capture production statistics (accessible at https://www.fao.org/fishery/statisticsquery/en/capture/capture_quantity), reported catch for shortfin make shark in the period 2010–2019 totaled 128,743 t, up from 86,912 t in the period 2000-2009 and 29,754 t in the period 1990-1999. In the 2010-2019 time frame, reported landings in the Atlantic Ocean and adjacent seas totaled 61,673 t (~48 percent of global reported catch), in the Pacific Ocean totaled 43,927 t (~34 percent of global reported catch), and in the Indian Ocean totaled 23,143 t (~ 18 percent of global reported catch). Reported landings, however, represent a substantial underestimate of actual catch because they do not fully account for mortalities that result from fisheries interactions, including sharks that are discarded dead, finned, or that experience post-release mortality. For instance, Clarke et al. (2006) estimated that shark biomass in the fin trade alone is three to four times higher than catch reported in the FAO capture production data. Therefore, impacts of commercial fishing fleets on the shortfin make shark are likely much greater than reported catch numbers suggest.

Data from across the species' range indicate that much of the catch of shortfin make sharks in longline fisheries is composed of immature individuals (N Atlantic: Biton-Porsmoguer 2018, Coelho et al. 2020a; S Atlantic: Barreto et al. 2016; NW Pacific: Ohshimo et al. 2016, Semba et al. 2021; E Pacific: Furlong-Estrada et al. 2017, Saldaña-Ruiz et al. 2019, Doherty et al. 2014; Indian: Winter et al. 2020, Wu et al. 2021). Exploitation of the juvenile

life stage reduces the proportion of the population that survives to maturity to reproduce. Due to the late age-atmaturity of the species, many years are required before conservation actions may influence the spawning population. Additionally, abundance indices based on the part of the population that is most vulnerable to fisheries mortality (immature individuals) can be out of phase with those based on the abundance of the spawning stock (e.g., CPUE and age-structured population models, respectively) for decades. For these reasons, the delay between identifying overutilization and addressing it can limit the effectiveness of mitigation and can make fisheries management for the shortfin make shark difficult.

Rates of at-vessel mortality, or mortality resulting from interactions with fishing gear prior to being brought onboard (also known as hooking or capture mortality), vary by fishing practice and gear type. Campana et al. (2016) estimated fisheries mortality of shortfin mako sharks in Northwest Atlantic pelagic longline fisheries targeting swordfish and tuna, in which the majority (88 percent) of hooks used were circle hooks. The types of leaders or branch lines were not reported. Shortfin make sharks were found to experience a mean at-vessel mortality rate of 26.2 percent, and another 23 percent of incidentally caught shortfin mako sharks were injured at haulback (Campana et al. 2016). The proportion of shortfin mako sharks that experienced at-vessel mortality in pelagic longlines was significantly higher than that of blue sharks (Prionace glauca), likely because shortfin mako sharks have very high oxygen requirements, and their ability to ram ventilate—or continuously force water across their gills to breathe, typically by swimming at speed—is compromised once hooked (Campana 2016; Campana et al. 2016). Data from Portuguese longline vessels targeting swordfish in the North and South Atlantic indicate at-vessel mortality rates of 35.6 percent for shortfin mako shark (Coelho et al. 2012). This fleet uses stainless steel J hooks and both monofilament and wire branch lines (Coelho et al. 2012). In the North Pacific, shortfin make sharks incidentally caught in the Hawaii deepset and American Samoa longline fisheries targeting tuna were found to experience an at-vessel mortality rate of 22.7 percent (Hutchinson et al. 2021). Prior to May 2022, the Hawaii deep-set fishery used circle hooks, stainless steel braided wire leader, and monofilament; the American Samoa longline fishery

uses circle hooks and all monofilament branch lines (Hutchinson et al. 2021). However, in May 2022, NMFS issued a final rule that prohibits the use of wire leader in the Hawaii deep-set longline fishery, which is anticipated to increase survivorship of incidentally caught sharks.

Post-release (or discard) mortality rates are more difficult to accurately assess, although tag-recapture and telemetry studies indicate that they can be relatively low for shortfin make sharks depending on factors such as hook type, hooking location, and handling. Reported estimates of postrelease mortality rate also depend on the duration over which survival is assessed. Any mortality related to capture and handling that occurs after the monitoring period would cause post-release mortality rates to be underestimated (Musyl *et al.* 2009, Musyl and Gilman 2019). Campana et al. (2016) estimated that shortfin make sharks (n=26) caught incidentally in Northwest Atlantic pelagic longlines have post-release mortality rates of 30-33 percent over ~50 days. Bowlby et al. (2021) also investigated post-release mortality in North Atlantic pelagic longline fleets, estimating a rate of 35.8 percent for the species over the first 30 days from 104 tagging events. The postrelease mortality rate of tagged shortfin mako sharks (n=35) after capture and release by pelagic longliners in the Northeast, Northwest, Equatorial, and Southwest Atlantic was estimated at 22.8 percent over the first 30 days (Miller et al. 2020). A telemetry study on post-release mortality rates of five shark species captured in the Hawaii deep-set and American Samoa tuna longline fisheries found relatively low post-release mortality rates for shortfin mako shark (6 percent), with only one mortality observed out of 18 tags that reported (Hutchinson et al. 2021). A Bayesian analysis of the post-release mortality rates from all sharks tagged (including shortfin make shark) found that post-release fate was correlated with the animal's condition at the vessel, handling method, and the amount of trailing gear left on the animals, whereby animals that were left in the water and had most of the gear removed had the lowest mortality rates (Hutchinson et al. 2021). Another telemetry study conducted by the WCPFC in three longline fisheries in the South Pacific (New Caledonia, Fiji and New Zealand) with much larger sample sizes (n = 57 shortfin mako shark tags) also found low post-release mortality rates for shortfin make sharks: 11.6 percent of the tagged, uninjured shortfin

make sharks died within the 60-day monitoring period of the tags, and this estimate increased to 63.2 percent for injured shortfin mako sharks (Common Oceans (ABNJ) Tuna Project 2019). Similar to conclusions from Hutchinson et al. 2021, survival rates were higher when trailing gear was minimized, particularly in relation to the size of the animal. Although the practice of hauling sharks on deck was not found to have contributed to mortality, the probability of injury is higher when sharks are hauled onboard, and injured sharks are less likely to survive (Common Oceans (ABNJ) Tuna Project 2019). This suggests that improvements to handling and release methods can help reduce post-release mortality in shortfin mako shark and other shark bycatch species.

In sum, bycatch mortality makes up a substantial amount of total fishery mortality that is not captured in reported landings data. Total nonlanded fishery mortality for shortfin mako sharks in the Canadian pelagic longline fishery was estimated at 49.3 percent (95 percent CI: 23-73 percent), indicating that even if retention of the species is prohibited, about half of shortfin make sharks hooked by this fleet would die during or after fishing (Campana et al. 2016). Given that other nations targeting swordfish and tuna in the Northwest Atlantic and other ocean basins use similar gear configurations as used in the study by Campana et al. (2016), similar un-reported mortality levels may be expected if landings of shortfin make shark were prohibited throughout its global range. Hook type, gear configuration, handling (i.e., bringing incidentally caught shortfin mako sharks on deck to remove gear) (Bowlby et al. 2021), and bait type (Coelho *et al.* 2012; Amorim *et al.* 2015; Fernandez-Carvalho et al. 2015) have been shown to influence catch and mortality rates of shortfin make sharks (see the Status Review Report for a detailed review of this information).

In the North Atlantic Ocean, shortfin mako sharks are incidentally caught mainly in pelagic and surface longlines, and to a lesser extent, purse seines, bottom trawls, and gillnets. There are no commercial fisheries targeting shortfin mako sharks in this region. Since 2017, and until only recently, ICCAT Contracting Parties and Cooperating Non-Contracting Parties (CPCs) have been required to release live North Atlantic shortfin make sharks in a manner that causes the least harm. Retention of dead North Atlantic shortfin mako sharks remained acceptable in many cases, and harvest of live individuals was only permitted under very limited circumstances.

Reported landings for all CPCs in the North Atlantic (including dead discards) did decline in recent years, though numbers remain high (3,281 t in 2015; 3,356 t in 2016; 3,199 t in 2017; 2,373 t in 2018: 1.882 t in 2019: 1.709 t in 2020) (SCRS 2021). Over 90 percent of recent shortfin make shark catch in the North Atlantic is attributable to Spain (longline fleet targeting swordfish), Morocco (longline fleet targeting swordfish and purse seine), and Portugal (longline fleet targeting swordfish), with Spain harvesting nearly half of the North Atlantic catch in 2019 (866 t reported). These three countries have each recently announced unilateral retention bans. In early 2021, Spain announced a moratorium on the landing, sale, and trade of North Atlantic shortfin make shark. The retention ban reportedly applies to 2021 catches from all Spanish vessels, whether operating in domestic water or on the high seas, and the ban on sale and trade extends to a 90 t stockpile of all make shark fins landed by Spanish vessels in 2020. Shortly afterwards, Portugal announced a moratorium on landings of shortfin make sharks caught in the North Atlantic high seas fisheries, the source of the majority of Portugal's mako shark catch. In February 2022, the government of Morocco announced a 5vear national prohibition on the fishing, storage, and trade of shortfin make shark. Due to at-vessel and post-release mortality, retention bans will not eliminate fishery mortality. However, because approximately 50 percent of catches would be expected to survive as discussed above, these retention bans may significantly reduce shortfin mako shark mortality in pelagic longline fleets operating in the North Atlantic, and therefore overall mortality in this region.

Shortfin mako sharks are incidentally caught by the U.S. pelagic longline fleets targeting swordfish and tuna (Thunnus spp.), including in the Gulf of Mexico and the Caribbean Sea. A total of 2,406 t of shortfin make shark was landed and sold by this fishery between 1985 and 2008, valued at \$4,562,402 (Levesque 2013). Commercial landings of incidentally caught shortfin make shark ranged from 17.6 t in 1985 to 266.8 t in 1993, with a mean of 100.24 t year ¹ (Levesque 2013). As described below in Inadequacy of Existing Regulatory Mechanisms, after the 2017 ICCAT stock assessment indicated that North Atlantic shortfin mako sharks were overfished and experiencing overfishing, the United States took immediate action to end overfishing and work towards

rebuilding of the stock through emergency rulemaking. These measures led to a reduction in North Atlantic shortfin make shark landings by the U.S. longline fleet, with 112 t landed in 2017, 42 t landed in 2018, and 33 t landed in 2019 (NMFS 2021). Shortfin mako shark catch in U.S. pelagic longlines represented only 0.8 percent of total international longline catch of the species across the entire Atlantic Ocean in 2019 (NMFS 2021), and due to the poor reporting of other ICCAT CPCs, this percentage is likely significantly lower. A detailed overview of other fleets that contribute to shortfin make shark mortality in the North Atlantic can be found in the Status Review Report.

Risk assessments have repeatedly found shortfin make sharks to be at high risk of overexploitation by pelagic longline fisheries in the North Atlantic. Using an ecological risk assessment, the inflection point of the population growth curve (a proxy for B_{MSY}), and IUCN Red List status, Simpfendorfer et al. (2008) found the shortfin make shark to have the highest risk among the pelagic shark species taken in Atlantic longline fisheries. Similar results were found by Cortés et al. (2010) in an ecological risk assessment of 11 pelagic elasmobranchs across the North and South Atlantic, which incorporated estimates of productivity (intrinsic rate of increase, r) and susceptibility to the fishery (a product of the availability of the species to the fleet, encounterability of the gear given the species' vertical distribution, gear selectivity, and postcapture mortality). The authors found the shortfin make shark to be at high risk of overexploitation (Cortés et al. 2010). In an expanded assessment, the shortfin make shark's low productivity (r=0.058 year⁻¹) and high susceptibility to capture (0.220, calculated as the product of four factors: availability of the species to the fleet, encounterability of the gear given the species' vertical distribution, gear selectivity, and postcapture mortality) continued to give the species one of the highest risks of overexploitation of sharks caught by Atlantic pelagic longline fleets (Cortés *et* al. 2015).

In the North Atlantic, fisheries mortality has led to substantial population declines, and the stock is currently both overfished and experiencing overfishing. ICCAT Recommendations 17–08 and 19–06 have required live shortfin make sharks to be released except in very limited circumstances since 2017, though reported landings are still high (1,709 t in 2020, inclusive of dead discards (SCRS 2021)). The ERA Team

considered whether a newly adopted retention prohibition (Recommendation 21–09) would be adequate to reduce fishing mortality and allow the stock to begin to rebuild, given that at-vessel mortality will not be addressed by this measure. Given the status of the stock, the continued high level of fishing effort, high catches, and low productivity, the ERA Team concluded, and we agree, that the best available scientific and commercial information indicates that overutilization of shortfin mako shark is occurring in the North Atlantic Ocean. Recent management measures may decrease the degree to which overutilization threatens the species over the foreseeable future (50 years), although this depends on whether current management measures are effectively implemented, and whether additional management measures, including measures addressing fishing gear and behavior, are implemented in the future (this is discussed further in Inadequacy of Existing Regulatory Mechanisms).

Shortfin make sharks are frequently incidentally caught in pelagic longlines in the South Atlantic, where fishing effort has been increasing since the 1970s (Barreto et al. 2016). Recent reported landings and dead discards of South Atlantic shortfin make shark by all ICCAT CPCs are as follows: 2,774 t in 2015; 2,765 t in 2016; 2,786 t in 2017; 3,158 t in 2018; 2,308 t in 2019; 2,855 t in 2020 (SCRS 2021). An analysis of historical catches in longline fishing fleets in the South Atlantic found three distinct phases of fishery exploitation: phase A (1979–1997), characterized by the use of deep multifilament line with J hooks to target tunas; phase B (1998-2007), during which monofilament lines and circle hooks were used to target sharks and tunas, and phase C (2008– 2011), during which several measures regulating shark fishing came into effect (Barreto et al. 2016). The authors found that standardized catch rates of shortfin mako shark from a zero-truncated model increased 8-fold in phase A (1979-1997), decreased by 55 percent in phase B (1998-2007), and increased 1.3-fold in phase C (2008-2011), even though nominal catch rates for all sharks combined were highest in phase B. Dramatic catch rate declines in phase B coincided with significant fishing effort increases as well as a lack of regulatory measures, and Barreto et al. (2016) conclude that shortfin make sharks are depleted in the South Atlantic.

Significant contributors to South Atlantic shortfin make shark landings as reported by the ICCAT SCRS are Spain, Namibia, Brazil, Portugal, and South Africa. Spanish longline fleets in the

South Atlantic reported shortfin make shark catches of 1,049 t in 2017, 1,044 t in 2018, 1,090 t in 2019, and 799 t in 2020 (SCRS 2021). The Spanish fleet has retained the vast majority of shortfin mako shark bycatch due to the high value of the species. Therefore, catches and landings have been roughly equivalent since the beginning of this fishery (Mejuto et al. 2009). In Brazil, pelagic longline vessels targeting tuna have been fishing since 1956, and part of the longline fleet shifted to targeting swordfish in 1994 (Lucena Frédou et al. 2015). Although there are no directed fisheries for shortfin make shark in the South Atlantic, the species is frequently retained due to its high value, and is one of eight shark species commonly caught in the Brazilian longline fleet (Lucena Frédou et al. 2015). Data from 2004-2010 indicate that make sharks (shortfin and longfin combined, though longfin are rarely caught) were the second most common shark, making up 5.4 percent of all individuals caught (Lucena Frédou et al. 2015). Reported catch has been increasing in Brazil over the past few years: 124 t in 2016, 275 t in 2017, 399 t in 2018, 739 t in 2019, and 542 t in 2020 (no discards have been reported) (SCRS 2021). The South African pelagic longline fleet targeting tuna and swordfish operates in South Africa's Exclusive Economic Zone (EEZ) where the Southeast Atlantic meets the Southwest Indian Ocean. Based on landings, logbook, and observer data, the South African pelagic longline fleet was estimated to catch 50,000 shortfin mako sharks in 2015, with less than 1,000 estimated to have been released in good condition (Jordaan et al. 2020). In total, 96 percent of hooked shortfin make sharks were retained, and of those discarded, 82 percent were dead (Jordaan et al. 2020). Most of the shortfin make shark catch occurred in waters of the Indian Ocean and was, therefore, reported to the IOTC; smaller quantities of the species are caught in Åtlantic waters (Jordaan et al. 2020). There have been steep increases in fishing effort (from 0.45 million hooks set in 2000 to 1.7 million hooks set in 2015) as well as shortfin make shark fishing mortality in the South African pelagic longline fleet (Jordaan et al. 2018). Additional information on fishing practices of other fleets that contribute to shortfin make shark mortality in the South Atlantic can be found in the Status Review Report.

In the South Atlantic, the shortfin make shark has an overall 19 percent probability of being overfished with overfishing occurring (ICCAT 2017). Data quality in the South Atlantic is poor, and the stock assessment in this region has high uncertainty. Therefore, given the high fishing effort and low productivity of the species, the ERA Team concluded, and we agree, that the best available scientific and commercial data indicate that overutilization may be occurring in the South Atlantic.

In the Western and Central Pacific Ocean, shortfin make sharks commonly interact with longline fisheries and are more rarely targeted by certain fleets. Fisheries information and catch data for this region are available from the WCPFC, and although historical catch data are lacking, reporting has improved in recent years with required reporting of catches of key shark species. Despite reporting requirements, recent catches of key shark species have not been provided to the WCPFC for a number of longline fleets, including Indonesia, which is the top shark fishing nation in the world (Dent and Clarke 2015; Okes and Sant 2019). Fleets with the highest reported numbers of shortfin make sharks caught in recent years (as reported in WCPFC data catalogs available at https://www.wcpfc.int/datacatalogue) include Taiwan, the United States (Hawaii), Japan, Spain, and New Zealand. In the western North Pacific, Taiwanese coastal and offshore longline fishing vessels mainly target dolphinfish (also known as mahi mahi; Coryphaena hippurus), tunas, and billfishes from April to October, and switch to targeting sharks by changing gear configuration from November to March (Liu et al. 2021a). Liu et al. (2021a) carried out a productivity-susceptibility analysis for these Taiwanese fleets, where intrinsic rate of population growth (r) was used to express productivity, and susceptibility was estimated by multiplying catchability, selectivity, and post-capture mortality. Based on the shortfin mako shark's low productivity (r = 0.0300) and high susceptibility (1.1754), the authors found the species to be at highest ecological risk. However, when conducting an integrated ERA (incorporating the ERA, IUCN Red List index, annual body weight variation trend, and the inflection point of population growth curve), Liu et al. (2021a) found the species to be in the least risk group, possibly because the average body weight of the species in the western North Pacific has not experienced significant decline. The authors found this result to be reasonable as the latest stock assessment for North Pacific shortfin make shark indicates that the stock is not overfished and overfishing is not occurring. The shortfin make shark is one of the most commonly

caught shark species in the Taiwanese large-scale tuna longline fleet. Taiwan's catch of mako sharks (shortfin and longfin) in all longline fleets as reported in WCPFC data catalogs are high in the most recent 6 years of data: 1,216 t in 2015; 1,073 t in 2016; 1,088 t in 2017; 1,146 t in 2018; 1,680 t in 2019; and 1,665 t in 2020.

While there are no directed commercial fisheries for shortfin mako sharks in Hawaii, the species is caught relatively frequently in the Hawaiibased pelagic longline fishery targeting swordfish in the shallow-set sector, and bigeve tuna (Thunnus obesus) in the deep-set sector (Walsh et al. 2009; Carvalho 2021). Substantially higher numbers of shortfin make sharks are caught in the deep-set sector than the shallow-set sector. From 1995-2006, shortfin mako sharks made up 2.9 percent of all observed shark catch in Hawaii-based pelagic longline fisheries, with higher nominal CPUE rates in the shallow-set sector than the deep-set sector (Walsh et al. 2009). Between 1995-2000 and 2004-2006, catch rates for shortfin make sharks were stable for the deep-set sector, and increased 389 percent in the shallow-set sector to 0.911 sharks per 1000 hooks (Walsh et al. 2009). Comparing the same two time periods, minimum estimates of shortfin mako shark mortality decreased in both the deep-set and shallow-set sectors (from 80.6 to 47 percent, and from 68 to 31.6 percent, respectively) (Walsh et al. 2009). This reduction in mortality may be a result of the prohibition of shark finning in 2000, and the requirement of the use of relatively large circle hooks rather than traditional J-hooks in the shallow-set sector beginning in 2004 (Walsh et al. 2009; Carvalho et al. 2014). Data from Hawaii and California-based Pelagic Longline Vessels Annual Reports (available at https:// www.fisheries.noaa.gov/resource/data/ hawaii-and-california-longline-fishery*logbook-summary-reports*) indicate that from 2008 to 2019, Hawaii longline fisheries have steadily increased the portion of make catch that is released alive, with 58 percent being released alive in 2008 and 89 percent being released alive in 2019. Data from the report also shows that from 2008 to 2019, mako sharks comprised, on average, only 0.71 percent of all species landed in the shallow-set and deep-set fisheries combined. Additional information on other fleets that contribute to shortfin make shark mortality in the Western and Central Pacific Ocean can be found in the Status Review Report.

Although historical catch data for the Western and Central Pacific are lacking,

reporting has improved in recent years with the implementation of conservation and management measures that require reporting of catches of key shark species. A noteworthy exception are catches from Indonesia, recognized as the top shark fishing nation in the world. Interactions with shortfin make shark commonly occur in pelagic longline fleets in this region. While RFMOs, and therefore landings data, fishing practices, and regulatory measures, are divided into the Eastern and Western and Central Pacific, abundance data in the Pacific are separated by North and South Pacific. Therefore, we take into consideration abundance data available for both the North and South Pacific when assessing overutilization of the Western and Central Pacific shortfin mako shark population. The latest stock assessment for shortfin make sharks in the North Pacific indicates that the stock is not overfished and overfishing is not occurring, and CPUE trends from the South Pacific indicate increasing shortfin mako shark abundance. Based on the best available scientific and commercial data on current and historical levels of fishing mortality and abundance, the ERA Team concluded that overutilization is not likely occurring in the Western and Central Pacific Ocean, and we agree.

In the Eastern Pacific Ocean, the species is mainly taken as bycatch in commercial longline, drift gillnet, and purse seine fleets (Read 2008). According to the Inter-American Tropical Tuna Commission's (IATTC) Report on the tuna fishery, stocks, and ecosystem in the Eastern Pacific Ocean in 2020, purse seine fisheries have contributed very little to the take of mako sharks (Isurus spp.) in the Eastern Pacific from 1993–2020 (estimated <3 t each year on average). Longline vessels are a more important source of fishery mortality for the genus in the Eastern Pacific Ocean. Estimated catch of mako sharks (Isurus spp.) was 2,882 t in 2018 and 1,927 t in 2019, and the total estimated catch in longlines from 1993-2019 was 36,036 t (IATTC 2020). The California/Oregon drift gillnet fishery targeting swordfish and thresher sharks incidentally catches shortfin make sharks, the large majority of which are retained. Annual landings of the species ranged from 278 t in 1987 to 31 t in 2006, and have annually declined since the late 1990s (Read 2008; Sippel et al. 2014). Analysis of NMFS observer records from 1990-2015 indicates that shortfin mako sharks make up only 4.92 percent of the total catch in this fishery (Mason et al. 2019). Within Mexico's

EEZ in the Pacific, shortfin make sharks are taken in the artisanal fishery and the pelagic longline fishery, and were historically taken in the drift gillnet fishery until 2010 (Sosa-Nishizaki et al. 2017). Gillnet and longline fleets in Ecuador and Peru also contribute to catch of the species in this region (Alfaro-Shigueto et al. 2010; Doherty et al. 2014; Martinez-Ortiz et al. 2015). Additionally, despite being defined as small-scale, Peruvian longline fisheries targeting dolphinfish have a high magnitude of fishing effort and proportion of juvenile shortfin make sharks landed; this may have a large effect on the population off of Peru. Additional information on other fleets that contribute to shortfin make shark mortality in the Eastern Pacific can be found in the Status Review Report.

While RFMOs, and therefore landings data, fishing practices, and regulatory measures, are divided into the Eastern and Western and Central Pacific, abundance data in the Pacific are separated by North and South Pacific. Therefore, we take into consideration abundance data available for both the North and South Pacific when assessing overutilization of the Eastern Pacific shortfin make shark population. The latest stock assessment for shortfin mako shark in the North Pacific indicates that the stock is not overfished and overfishing is not occurring. CPUE trends available from a variety of fisheries in the South Pacific indicate population increases, although a stock assessment is not available for this region. Despite this lack of a cohesive population model, the available data indicate flat or increasing abundance trends in the South Pacific. Based on the best available scientific and commercial data on current and historical levels of fishing mortality and abundance, the ERA Team concluded, and we agree, that overutilization is not demonstrably occurring in the Eastern Pacific Ocean, despite variation in the certainty associated with estimates.

In the Indian Ocean, shortfin mako sharks are caught in pelagic longline, gillnet, and purse seine fleets, with the majority of catch coming from longlines targeting swordfish and sharks. Nominal reported catches of sharks in the IOTC Convention area have generally been increasing since the 1950s, though reporting of shark catches has been very irregular and information on shark catch and bycatch is considered highly incomplete (Murua et al. 2018). Fisheries catch data for the Indian Ocean are available from the IOTC, which requires CPCs to annually report shortfin mako shark catch data (IOTC Resolutions 17/05, 15/01, and 15/02).

However, prior to the adoption of resolution 05/05 in 2005 (superseded by resolution 17/05 in 2017), there was no requirement for sharks to be recorded at the species level in logbooks. It was not until 2008 that some statistics became available on shark catch, mostly representing retained catch and not accounting for discards (IOTC 2018). Several countries continue to not report on their interactions with bycatch species as evidenced by high rates of by catch reported by other fleets using similar gear configurations (IOTC 2018). When catch statistics are provided, they may not represent total catches of the species, but those simply retained on board, with weights that likely refer to processed specimens (IOTC 2018). Misidentification of shark species is also a common problem, and reporting by species is very uncommon for gillnet fleets where the majority of shark catches are reported as aggregates (IOTC 2020). Reported shark catches dropped significantly after 2017 when India stopped reporting aggregated shark catches and did not replace that reporting with detailed reports by species. Decreases in reported shark catches by Mozambique and Indonesia are thought to represent similar reporting issues (IOTC 2020). In sum, although reporting has improved substantially in recent years, there is a lack of historical data that does not allow for establishment of long-term trends, and current reported catches continue to be incomplete and largely underestimated. The major contributors to make shark (longfin and shortfin combined) catch reported to IOTC are Japan, Madagascar, Indonesia, Spain, Sri Lanka, Pakistan, Taiwan, South Africa, Portugal, and Guinea. A detailed overview of fleets that contribute to shortfin make shark mortality in the Indian Ocean can be found in the Status Review Report.

Using the methodology of Cortés et al. (2010), a preliminary Productivity-Susceptibility Analysis for sharks caught in IOTC longline fisheries revealed that shortfin make sharks have among the highest vulnerability to overexploitation in this fishery due to the species' low productivity (λ =1.061) and high susceptibility (0.929) (Murua et al. 2012). In an updated ecological risk assessment of IOTC longline, gillnet, and purse seine fisheries, Murua et al. (2018) found that the most vulnerable species to the IOTC pelagic longline fleet is the shortfin make shark based on its low productivity (λ =1.059) and high susceptibility (0.867). Shortfin mako sharks had lower susceptibility to catch in the purse seine and gillnet

fisheries (0.129 and 0.318, respectively) and were therefore found to be less vulnerable to overexploitation by these fleets (Murua et al. 2018). The postcapture mortality rate in Indian Ocean purse seine fleets was reduced between the 2012 and 2018 assessments due to the European fleet implementing safe release best practices in 2014, but is still quite high for shortfin make sharks (approximately 55 percent) (Murua et al. 2018). Post-capture mortality represents the proportion of captured animals that die as a result of interaction with the gear, calculated as the sum of landings and dead discards (Cortes et al. 2010).

Available preliminary stock assessments for shortfin make sharks in the Indian Ocean indicate that overfishing is occurring but the stock is not vet overfished. Underreporting of catch is suspected to be continuing in this region, and the ERA Team therefore had low certainty that these assessments accurately reflect the status of the species here. However, recent CPUE trends in certain fleets indicate increasing abundance trends in this region. The ERA Team concluded that, while overutilization in commercial fisheries is likely impacting shortfin mako sharks in the Indian Ocean, the severity of this threat is highly uncertain. The best available scientific and commercial information on current and historical levels of fishing mortality and abundance indicates that overutilization is likely impacting the species in this region to some degree, and will continue to impact the species in this region over the foreseeable future (50 years)

Demand for shark products, specifically meat and fins, has rapidly increased over the last 4 decades and has led to the overexploitation of shark populations worldwide. While trade in shark fins appears to have decreased slightly since the early 2000s, the trade in shark meat has grown over the last decade or so (Dent and Clarke 2015). In fact, domestic shark meat consumption in India is indicated to be the main driver of local shark harvest rather than the global fin trade (Karnad et al. 2020). The vast majority of shark fins in international trade are imported into and consumed in East and Southeast Asia, including China, Hong Kong, Taiwan, Singapore, Malaysia, and Vietnam, while the largest importers and consumers of shark meat include Italy, Brazil, Uruguay, and Spain (Dent and Clarke 2015). Spain, Indonesia, Taiwan, and Japan are the major shark fin exporting producers, and as the trade in shark meat has increased in recent years, these producers have also begun exporting large volumes of shark meat to the markets in Italy and Brazil (Dent and Clarke 2015). While available data on the trade in shark products are incomplete due to inconsistent identification of species and tracking of product types and volumes, FAO statistics conservatively estimate the average declared value of total world shark fin imports at \$377.9 million per year from 2000-2011, with an average annual volume imported of 16,815 t (Dent and Clarke 2015). Annual average figures for shark meat from 2000-2011 were 107,145 t imported, worth \$239.9 million (Dent and Clarke 2015). Quantifying the amount of individual sharks harvested for the international shark trade is more difficult given that a substantial proportion of harvest is illegal, unregulated, or unreported (Clarke et al. 2006b). Using shark fin trade data to estimate the total number of sharks traded worldwide, Clarke et al. (2006b) found that between 26 and 73 million individual sharks of all species are traded annually (median = 38 million each year), with a median biomass estimate of 1.70 million t per year (range: 1.21-2.29 million t each

Shortfin mako sharks are commonly retained for their highly valued meat when incidentally caught, with fins often kept as a by-product (Fowler et al. 2021). The meat is utilized fresh, frozen, smoked, dried, and salted for human consumption (CITES 2019; Dent and Clarke 2015). Shortfin mako shark liver oil, teeth, jaws, and skin are also traded, though most of these products are of lower value and are not traded in significant quantities (CITES 2019).

The shortfin mako shark is a preferred species in the Hong Kong fin market, one of the largest fin trading markets in the world (Fields et al. 2018). Clarke et al. (2006a) analyzed 1999-2001 Hong Kong trade auction data in conjunction with species-specific fin weights and genetic information to estimate the annual number of globally traded shark fins. The authors estimated that the shortfin mako shark makes up approximately 2.7 percent (95 percent probability interval: 2.3-3.1 percent) of the Hong Kong shark fin trade, the fourth highest proportion of auctioned fin weight after blue (17.3 percent), hammerhead (Sphyrna zygaena or S. lewini, 4.4 percent) and silky (Carcharhinus falciformis, 3.5 percent) sharks. This translates to an estimated 300,000-1,000,000 shortfin make sharks utilized in the global shark fin trade each year, totaling between 20,000 and 55,000 t in biomass (Clarke et al. 2006b). Although these data are fairly dated, more recent studies demonstrate the continued prevalence of shortfin make

shark fins in international trade. Fields et al. (2018) found shortfin make shark to be the ninth most commonly traded species in Hong Kong based on random samples of fin trimmings from retail markets, making up 2.77 percent of fin trimming samples and comprising 0.6 percent of modeled trimmings. In another recent study, shortfin make shark fins made up 4.16 percent and 2.37 percent of samples taken in the fin markets of Guangzhou, the largest fin trade hub in mainland China, and Hong Kong, respectively (Cardeñosa et al. 2020).

Shortfin mako sharks were listed under Appendix II of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) effective November 26, 2019. As such, exports of the species must be found to be non-detrimental to the survival of the species in the wild and the specimen must have been legally acquired. As the numbers presented above predate the CITES listing of shortfin make sharks, current levels of exploitation for the international trade in meat and fins may be lower than prior to the listing (this regulatory measure is discussed further in Inadequacy of Existing Regulatory Mechanisms). With the trade in shark meat on the rise, the preference for shortfin mako shark meat in addition to their continued prevalence in the fin trade presents a concern for overutilization of the species.

Several ERA Team members cited the estimation by Clarke et al. (2006b) that 300,000–1,000,000 shortfin make sharks may be utilized in the global shark fin trade each year in their assessment of this threat. Although this is not a recent study, and recent regulatory mechanisms may reduce pressure from the fin trade on this species, this estimate is still cause for concern given the low productivity of the species. Considering the recent declines in the fin trade and increases in the meat trade, the ERA Team generally concluded, and we agree, that the preference for shortfin make shark meat (in addition to fins) presents a concern for overutilization of the species in the future.

After considering the best available scientific and commercial data, several conclusions are indicated. Overall, although catch and mortality data are underreported globally, with very low confidence in data from both the Indian and South Atlantic Oceans, the ERA Team recognized the ESA's requirement to consider the best scientific and commercial data available, as summarized above and detailed in the Status Review Report. The majority of

ERA Team members concluded that overutilization of the shortfin make shark for commercial purposes (in both fisheries and trade) is not likely currently significantly contributing to the species' status but will likely contribute to the extinction risk of the species in the foreseeable future as they defined it, especially if management measures are inadequate. We agree with the ERA Team that overutilization for commercial purposes is not likely contributing significantly to the shortfin mako shark's risk of extinction now. However, over the foreseeable future of 50 years that we have determined is more appropriate to apply for this species, we conclude that overutilization for commercial purposes is likely to contribute to its risk of extinction. Recent management measures in the North Atlantic (including retention prohibitions adopted by ICCAT and by the top three shortfin make shark-catching nations in the region) indicate increasing international efforts to reduce the effects of fishing mortality on the species in this region. Specifically, Recommendation 21-09 prohibits harvest of live individuals (previously allowed under limited circumstances) and contains strong provisions to improve data reporting, and particularly, the catch reporting of live releases and fish discarded dead. The measure does not require changes to fishing behavior or gear, and therefore will not address at-vessel or post-release mortality of incidentally caught shortfin mako sharks. Because of ICCAT's track record of taking multilateral conservation and management actions for the stock in response to indications of declining status, we have a reasonable basis to predict that similar or additional measures are likely to be continued or taken, as needed, to ensure ICCAT's objectives of ending overfishing and rebuilding the stock to levels that support MSY are met. While it is likely that the level of overutilization in this region will decline to some degree over the foreseeable future due to these efforts, it is unclear if Recommendation 21-09 will reduce mortality to a point that will allow the North Atlantic stock to rebuild. The low productivity of the shortfin mako shark means that the biological response to the measure will likely not be detectable for many years, despite assessment efforts. Therefore, at this time it is not possible to assess the adequacy of this measure to address the ongoing threat of overfishing in the North Atlantic. In the South Atlantic Ocean, fishing effort has been increasing since the 1970s and there are no specific management measures at the international level to address fishing mortality in this region. This indicates that overutilization may increasingly impact the species over the foreseeable future in this region. In the Indian Ocean, overutilization will continue to impact the species over the foreseeable future. Shortfin make sharks in the Pacific Ocean are not subject to overutilization at this time and there is no indication that this will change significantly over the foreseeable future.

Recreational fishermen target shortfin mako sharks in certain regions due to the high quality of their meat and the strong fight experienced by the angler. In the U.S. Atlantic, recreational landings of shortfin make sharks have been significantly reduced after management measures were implemented in 2018 and 2019. In the Pacific, both U.S. and Australian recreational fisheries for the species are largely catch-and-release. Further, population-level impacts of recreational fishing at a global scale are unlikely to occur due to vessel limitations that prevent the vast majority of the "fleet" from accessing the whole of the species' habitat. For these reasons, the ERA Team unanimously concluded that the best available scientific and commercial data indicate that recreational fishing is unlikely to contribute significantly to the species' risk of extinction now or in the foreseeable future as they defined it. We agree that recreational fishing is not contributing significantly to the species' risk of extinction now. Over the foreseeable future of 50 years that we have determined is more appropriate to apply for this species, we also find that recreational fishing is not likely to significantly contribute to the shortfin mako shark's risk of extinction because there is no basis to predict that the impact of recreational fisheries on the species will change over the extended time horizon.

Disease and Predation

Shortfin make sharks are known to host a number of parasites, but the ERA Team found no evidence that disease is impacting the status of the species, nor any indication that disease may influence the species' status in the foreseeable future.

The shortfin make shark is a large apex predator with few natural predators. Given current population estimates and distribution, impacts from predation on a global scale are not likely to affect the species' extinction risk. While climate change may cause changes to the marine food web (and therefore, potentially influence

predation on juvenile shortfin make sharks) over the next several decades, the ERA Team could not accurately predict how these changes may impact the species.

The ERA Team concluded that the best available scientific and commercial information indicates that neither disease nor predation are factors that are contributing or will likely contribute significantly to the species' extinction risk now or in the foreseeable future as they defined it. We agree that neither disease nor predation are contributing significantly to the species' extinction risk now. Over the foreseeable future of 50 years that we have determined is more appropriate to apply for this species, we also find that this factor is not likely to significantly contribute to the shortfin mako shark's risk of extinction because there is no basis to predict that this factor will change over the extended time horizon.

Inadequacy of Existing Regulatory Mechanisms

The ERA Team evaluated existing regulatory mechanisms to determine whether they may be inadequate to address threats to the shortfin mako shark from overutilization. Below is a description and evaluation of current and relevant domestic and international management measures that affect the shortfin mako shark. More detailed information on these management measures can be found in the Status Review Report.

U.S. Domestic Regulatory Mechanisms

The U.S. Secretary of Commerce has the authority to manage highly migratory species (HMS) in the U.S. EEZ of the Atlantic Ocean, Gulf of Mexico, and Caribbean Sea (16 U.S.C. 1811 and 16 U.S.C. 1854(f)(3)). The Atlantic HMS Management Division within NMFS develops regulations for Atlantic HMS fisheries and primarily coordinates the management of HMS fisheries in federal waters (domestic) and the high seas (international), while individual states establish regulations for HMS in state waters. However, federally permitted shark fishermen are required to follow federal regulations in all waters, including state waters, unless the state has more restrictive regulations. For example, the Atlantic States Marine Fisheries Commission (ASMFC) developed an interstate coastal shark Fisheries Management Plan (FMP) that coordinates management measures among all states along the Atlantic coast (Florida to Maine) in order to ensure that the states are following federal regulations. This interstate shark FMP became effective in 2010.

Shortfin make sharks in the Atlantic are managed under the pelagic species complex of the Consolidated Atlantic HMS FMP. The first Atlantic Shark FMP of 1993 classified the status of pelagic sharks as unknown because no stock assessment had been conducted for this complex. At that time, MSY for pelagic sharks was set at 1,560 t dressed weight (dw), which was the 1986-1991 commercial landings average for this group. However, as a result of indications that the abundance of Atlantic sharks had declined, commercial quotas for pelagic sharks were reduced in 1997. The quota for pelagic sharks was then set at 580 t. In 1999, the U.S. FMP for Atlantic Tunas, Swordfish, and Sharks implemented the following measures affecting pelagic sharks: (1) reducing the recreational bag limit to one Atlantic shark per vessel per trip, with a minimum size of 137 cm fork length for all sharks; (2) increasing the annual commercial quota for pelagic sharks to 853 t dw, apportioned between porbeagle (92 t), blue sharks (273 t dw), and other pelagic sharks (488 t dw), with the pelagic shark quota being reduced by any overharvest in the blue shark quota; and (3) making bigeyed sixgill (Hexanchus nakamurai), bluntnose sixgill (Hexanchus griseus), broadnose sevengill (Notorynchus cepedianus), bigeye thresher, and longfin mako sharks, among other species, prohibited species that cannot be retained.

The management measures for the conservation and management of the domestic fisheries for Atlantic swordfish, tunas, sharks, and billfish are published in the 2006 Consolidated HMS FMP and implementing regulations at 50 CFR part 635 (71 FR 58058, October 2, 2006; NMFS 2006). Since 2006, this FMP has been amended 12 times, with four additional amendments currently under development. Amendment 2, finalized in June 2008, requires that all shark fins remain naturally attached through landing in both the commercial and recreational fisheries (73 FR 35778, June 24, 2008; corrected in 73 FR 40658, July 15, 2008). Limited exceptions to this requirement allowed by Amendment 9 (80 FR 73128, November 24, 2015) do not apply to shortfin make sharks.

Any fisherman who fishes for, retains, possesses, sells, or intends to sell, Atlantic pelagic sharks, including shortfin make sharks, needs a Federal Atlantic Directed or Incidental shark limited access permit. Generally, directed shark permits (which do not authorize the retention of shortfin make sharks at this time) allow fishermen to target sharks while incidental permits

allow fishermen who normally fish for other species to land a limited number of sharks. The permits are administered under a limited access program and NMFS is no longer issuing new shark limited access permits. To enter the directed or incidental shark fishery, fishermen must obtain a permit via transfer from an existing permit holder who is leaving the fishery. Until recently, under a directed shark permit, there was no numeric retention limit for pelagic sharks, subject to quota limitations (see below for a description of a recent final rule regarding the retention limit for shortfin make sharks). An incidental permit allows fishermen to keep up to a total of 16 pelagic or small coastal sharks (all species combined) per vessel per trip. Authorized gear types include: pelagic or bottom longline, gillnet, rod and reel, handline, or bandit gear. All fins must remain naturally attached. The annual quota for pelagic sharks (other than blue sharks or porbeagle sharks) is currently 488.0 t dw (Amendment 2 to the 2006 Consolidated Atlantic HMS FMP (73 FR 35778, June 24, 2008; corrected version 73 FR 40658, July 15, 2008)).

NMFS monitors the catch of each of the different shark species and complexes in relation to its respective annual quota and will close the fishing season for each fishery if landings reach, or are projected to reach, an 80 percent threshold of the available quota, and are also projected to reach 100 percent of the available quota before the end to the fishing year. Atlantic sharks and shark fins from federally permitted vessels may be sold only to federally permitted dealers; however, all sharks must have their fins naturally attached through offloading. The head may be removed and the shark may be gutted and bled, but the shark cannot be filleted or cut into pieces while onboard the vessel. Logbook reporting is required for selected fishermen with a federal commercial shark permit. In addition, fishermen may be selected to carry an observer onboard, and some fishermen are subject to vessel monitoring systems depending on the gear used and locations fished. Since 2006, bottom longline and gillnet fishermen fishing for sharks have been required to attend workshops to learn how to release sea turtles and protected species in a manner that maximizes survival. In 2017, these workshops were modified to include a section on releasing prohibited shark species. Additionally, NMFS published a final rule on February 7, 2007 (72 FR 5633), that requires participants in the Atlantic shark bottom longline fishery to possess, maintain, and utilize handling and release equipment for the release of sea turtles, other protected species, and prohibited shark species. In an effort to reduce bycatch, NMFS has also implemented a number of time/area closures with restricted access to fishermen with HMS permits who have pelagic longline gear onboard their vessel.

The HMS Management Division also published an amendment to the 2006 Consolidated HMS FMP that specifically addresses Atlantic HMS fishery management measures in the U.S. Caribbean territories (77 FR 59842, October 1, 2012). Due to substantial differences between some segments of the U.S. Caribbean HMS fisheries and the HMS fisheries that occur off the mainland of the United States (including permit possession, vessel size, availability of processing and cold storage facilities, trip lengths, profit margins, and local consumption of catches), the HMS Management Division implemented measures to better manage the traditional small-scale commercial HMS fishing fleet in the U.S. Caribbean Region. Among other things, this rule created an HMS Commercial Caribbean Small Boat (CCSB) permit, which: allows fishing for and sales of big-eye, albacore, yellowfin, and skipjack tunas, Atlantic swordfish, and Atlantic sharks within local U.S. Caribbean market; collects HMS landings data through existing territorial government programs; authorizes specific gears; is restricted to vessels less than or equal to 45 feet (13.7 m) length overall; and may not be held in combination with any other Atlantic HMS vessel permits. Until 2021, fishermen who held the CCSB permit were prohibited from retaining any Atlantic sharks. However, at this time, fishermen who hold the CCSB permit are prohibited from retaining shortfin make sharks, and are restricted to fishing for authorized sharks with only rod and reel, handline, and bandit gear. Both the CCSB and Atlantic HMS regulations have helped protect shortfin make sharks while in the Northwest Atlantic Ocean, Gulf of Mexico, and Caribbean Sea through permitting, monitoring, quotas, and retention restrictions.

After the 2017 ICCAT stock assessment indicated that North Atlantic shortfin make sharks were overfished and experiencing overfishing, the United States took action to end overfishing and take steps toward rebuilding the stock through emergency rulemaking in March 2018. The measures immediately required release of all live shortfin make sharks caught by commercial pelagic longliners

with a minimum of harm while giving due consideration to the safety of crew members, and only allowed retention in pelagic longline gear if the shortfin mako shark was dead at haulback. The measures required commercial fishermen using non-pelagic longline gear (e.g., bottom longline, gillnet, handgear) to release all shortfin mako sharks, alive or dead, with a minimum of harm while giving due consideration to the safety of crew members. For recreational fisheries, the emergency rulemaking increased the minimum size limit for both male and female shortfin mako sharks to 83 inches FL. These temporary measures were replaced by long-term management measures finalized as Amendment 11 to the 2006 Consolidated HMS FMP in March 2019. The final management measures for commercial fisheries allowed retention of shortfin make sharks caught with longline or gillnet gears if sharks were dead at haulback. Further, vessels with pelagic longline gear were required to have a functional electronic monitoring system to verify condition for compliance purposes. For recreational fisheries, the minimum size limit was increased from 54 inches to 71 inches FL for males and 83 inches FL for females, and the use of circle hooks was required for all recreational shark fishing. These measures led to the reduction of the United States' total landings of North Atlantic shortfin mako shark (commercial and recreational) from 302 t in 2017, to 165 t in 2018, to 57 t in 2019, with 2 t of dead discards, an 81 percent reduction from 2017. In 2020, U.S. recreational landings of North Atlantic shortfin mako shark were 24 t, reduced by over 90 percent from the 2013-2017 average.

Following the adoption of Recommendation 21-09 at the November 2021 ICCAT annual meeting (described further below), NMFS published a final rule to implement a flexible shortfin mako shark retention limit with a default limit of zero in all commercial and recreational HMS fisheries (87 FR 39373; July 1, 2022). The rule meets domestic management objectives, implements Recommendation 21-09, and acknowledges the possibility of future retention (limited retention of shortfin mako sharks may be allowed in 2023 and future years if ICCAT determines that fishing mortality is at a low enough level North Atlantic-wide to allow retention consistent with the conservation objectives of the recommendation). The rule, effective July 5, 2022, requires that all commercial and recreational fishermen

release all shortfin make sharks, whether dead or alive, at haulback. Any sharks released alive must be released promptly in a manner that causes the least harm to the shark.

In the U.S. Pacific, HMS fishery management is the responsibility of adjacent states and three regional management councils that were established by the Magnuson-Stevens Fishery Conservation and Management Act (MSA): the Pacific Fishery Management Council (PFMC), the North Pacific Fishery Management Council (NPFMC), and the Western Pacific Regional Fishery Management Council (WPRFMC). Based on the range of the shortfin make shark, only the PFMC and WPRFMC directly manage the species.

The PFMC's area of jurisdiction is the EEZ off the coasts of California, Oregon, and Washington. Prior to the development of a West Coast-based FMP for HMS, the fisheries were managed by the states of California, Oregon, and Washington, although some federal laws also applied. In late October 2002, the PFMC adopted its FMP for U.S. West Coast HMS Fisheries. This FMP's management area also covers adjacent high seas waters for fishing activity under the jurisdiction of the HMS FMP. The final rule implementing the HMS FMP was published in the Federal Register on April 7, 2004 (69 FR 18443). Since its implementation, this FMP has been amended five times, most recently in 2018. The FMP requires a federal permit for all commercial HMS vessels that fish for HMS off of California, Oregon or Washington, or land HMS in these states. The permit is endorsed with a specific endorsement for each gear type to be used, and any commercial fisher may obtain the required gear endorsements. Legal HMS gear includes harpoon, surface hook and line, large mesh drift gillnet, purse seine, and pelagic longline; however, the use of these gears are subject to state regulatory measures. For commercial passenger recreational fishing vessels, a federal permit is required by the FMP. though existing state permits or licenses for recreational vessels can meet this requirement. Legal recreational gear includes rod-and-reel, spear, and hook and line. Per the FMP, due to the stock's vulnerability, possible importance of the U.S. West Coast EEZ as nursery habitat, and poorly known total catches and extent of the stock, the recommended harvest guideline for shortfin mako sharks is 150 t round weight. This harvest guideline is a general objective, not a quota. Although attainment of a harvest guideline doesn't require management action such as closure of

the fishery, it does prompt a review of the fishery.

The WPRFMC's area of jurisdiction is the EEZs of Hawaii, Territories of American Samoa and Guam, Commonwealth of the Northern Mariana Islands, and the Pacific Remote Island Areas, as well as the domestic fisheries that occur on the adjacent high seas. The WPRFMC developed the Fishery Ecosystem Plan for Pacific Pelagic Fisheries of the Western Pacific Region (FEP; formerly the Fishery Management Plan for the Pelagic Fisheries of the Western Pacific Region) in 1986 and NMFS, on behalf of the U.S. Secretary of Commerce, approved the Plan in 1987. Since that time, the WPRFMC has recommended, and NMFS has approved, numerous amendments to the Plan as necessary for conservation and management purposes. The WPRFMC manages HMS fisheries pursuant to the FEP, and species that are managed under FMPs or FEPs are called Management Unit Species (MUS), and typically include those species that are caught in quantities sufficient to warrant management or specific monitoring by NMFS and the Council. In the FEP, shortfin make sharks are designated as a Pelagic MUS and, thus, are subject to regulations under the FEP. These regulations are intended to minimize impacts to targeted stocks as well as protected species. Fishery data are also analyzed in annual reports and used to amend the FEP as necessary.

In addition to fishing regulations for highly migratory species, the United States has implemented several significant laws for the conservation and management of sharks. The Tuna Conventions Act of 1950, Atlantic Tunas Convention Act of 1975, and Western and Central Pacific Fisheries Convention Implementation Act (enacted in 2007) authorize the U.S. Secretary of Commerce to promulgate regulations for U.S. vessels that fish for tuna or tuna-like species in the IATTC, ICCAT, and WCPFC Convention areas, respectively. The MSA, originally enacted in 1976, is the primary law governing marine fisheries management in U.S. federal waters (3-200 miles offshore), and aims to prevent overfishing, rebuild overfished stocks, increase long-term economic and social benefits, and ensure a safe and sustainable supply of seafood. The MSA created eight regional fishery management councils, whose main responsibility is the development and subsequent amendment of FMPs for managed stocks. The MSA requires NMFS to allocate both overfishing restrictions and recovery benefits fairly and equitably among sectors of the

fishery. In the case of an overfished stock, NMFS must establish a rebuilding plan through an FMP or amendment to such a plan. The FMP or amendment to such a plan must specify a time period for ending overfishing and rebuilding the fishery that shall be as short as possible, taking into account the status and biology of the stock, the needs of fishing communities, recommendations by international organizations in which the United States participates, and the interaction of the overfished stock within the marine ecosystem. The rebuilding plan cannot exceed ten years, except in cases where the biology of the stock, other environmental conditions, or management measures under an international agreement in which the United States participates dictate otherwise.

The Shark Finning Prohibition Act of 2000 prohibits any person under U.S. jurisdiction from: (i) engaging in the finning of sharks; (ii) possessing shark fins aboard a fishing vessel without the corresponding carcass; and (iii) landing shark fins without the corresponding carcass, among other things. The Shark Conservation Act of 2010 strengthened shark finning measures by prohibiting any person from removing shark fins at sea (with a limited exception for smooth dogfish, Mustelus canis); or possessing, transferring, or landing shark fins unless they are naturally attached to the corresponding carcass.

Management measures implemented in response to the status of the North Atlantic shortfin mako shark stock were finalized in March 2019, and have been effective in reducing U.S. landings of the species in this region (both recreationally and commercially) as previously discussed. NMFS recently published a final rule to implement ICCAT Recommendation 21-09, requiring that all U.S. commercial and recreational fishermen release all shortfin mako sharks, whether dead or alive, at haulback. The adequacy of this retention prohibition cannot be assessed at this time; as data for each fishing year is not reported until the following calendar year, the effect of this measure will not be easily assessed until 2024 when the landings and discard data from 2023 can be analyzed. In the Pacific, the available stock assessment for the North Pacific region indicates that the species is neither overfished nor experiencing overfishing (ISC Shark Working Group 2018). For the foregoing reasons, it is likely that U.S. domestic fisheries management measures are adequate to address threats of overfishing to the species in U.S. waters. With regard to the fin and meat trade, declines in U.S. exports of shark fins

followed implementation of both the Shark Finning Prohibition Act and the Shark Conservation Act, and recent declines in the mean value of U.S. exports per metric ton have been reported by NMFS. Additionally, 14 U.S. states and three U.S. territories have enacted legislation controlling shark finning by banning possession and sale of shark fins (see details in the Status Review Report). These state laws have reduced U.S. landings of sharks and therefore U.S. trade and consumption of shark fins, although it is important to note that the United States has traditionally played a relatively minimal role in the global shark fin trade (0.3 and 0.4 percent of global imports and exports in U.S. dollars according to Ferretti et al. 2020). Measures that prohibit the possession and sale of shark fins may provide some limited conservation benefit to sharks, including the shortfin make shark, by discouraging the landing of any sharks. The ERA Team therefore concluded that the best available scientific and commercial data indicate that U.S. domestic regulatory measures are adequate to manage impacts from fisheries on the species in U.S. waters, as evidenced by the reduction in U.S. shortfin mako shark catch (commercial and recreational) in the Atlantic following the 2017 ICCAT stock assessment, stable population status in the North Pacific, and strong prohibitions on shark finning for those subject to U.S. jurisdiction. We agree with their assessment.

International Regulatory Mechanisms

Despite adequate management in U.S. waters, the ERA Team concluded that regulatory measures to address threats of incidental catch, targeted catch (in certain limited areas and fleets), and trade across the species' range may not be adequate in certain regions.

RFMOs that manage HMS play perhaps the most significant role in regulating catch and mortality of shortfin mako sharks in commercial fisheries worldwide. Of the four major RFMOs that manage shortfin mako sharks, only ICCAT has management measures specific to the species, while IATTC, WCPFC, and IOTC have general shark management measures.

ICCAT is the main international regulatory body for managing shortfin make sharks on the high seas in the Atlantic Ocean. In 2004, following the development and implementation of the International Plans of Action for Conservation and Management of Sharks (IPOA-Sharks), ICCAT adopted Recommendation 04–10 requiring CPCs to annually report data for catches of

sharks, including available historical data. This Recommendation specifically called for the SCRS to review the assessment of shortfin make sharks and recommend management alternatives for consideration by the Commission, and to reassess the species no later than 2007. In 2005, ICCAT adopted Recommendation 05-05, which amended Recommendation 04-10 by requiring CPCs to annually report on their implementation of the Recommendation, and instructing those that have not yet implemented this recommendation to reduce North Atlantic shortfin mako shark mortality to implement it and report to the Commission. In 2006, ICCAT adopted Recommendation 06-10, which further amended Recommendation 04-10 and called for a shortfin make shark stock assessment in 2008. A supplemental Recommendation by ICCAT (07–06, adopted in 2007 and entered into force in 2008) called for CPCs to submit catch data including estimates of dead discards and size frequencies in advance of SCRS assessments, to take appropriate measures to reduce fishing mortality for the North Atlantic shortfin mako shark, and to implement research on pelagic sharks in the Convention area to identify potential nursery areas. Recommendation 10-06 (adopted in 2010 and entered into force in 2011) instructed CPCs to report on how they have implemented the three recommendations described above, particularly steps they have taken to improve data collection for direct and incidental catches. It also recommended that CPCs that do not report catch data for shortfin make sharks be prohibited from retaining the species, and that the SCRS conduct a stock assessment for shortfin mako sharks in 2012. Recommendation 14-06 (adopted in 2014 and entered into force in 2015) replaced and repealed Recommendations 05-05 and 10-06, among others, and it calls for CPCs to improve data collection for shortfin make shark and report information on domestic catch of shortfin make shark to ICCAT and encourages CPCs to undertake research on biology and life history of the shortfin make shark.

Based on the 2017 shortfin mako shark stock assessment, which concluded there was a 90 percent probability of the stock being in an overfished state and experiencing overfishing (as discussed previously in *Abundance and Trends*), the Commission adopted Recommendation 17–08 (adopted in 2017 and entered into force in 2018), requiring CPCs to release North Atlantic shortfin mako sharks in

a manner that causes the least harm. Retention of dead North Atlantic shortfin mako sharks remained acceptable in many cases, and harvest of live shortfin was only permitted under very limited circumstances. In 2019, the SCRS carried out new projections for North Atlantic shortfin make shark through 2070 (two generation lengths) at the Commission's request (projections are described above in Abundance and Trends). Multiple TAC options with associated time frames and probabilities of rebuilding were presented to the Commission. Based on the resulting negative projections and high susceptibility of the species to overexploitation, and to accelerate the rate of recovery and to increase the probability of success, the SCRS recommended that the Commission adopt a non-retention policy without exception. While a non-retention policy would ostensibly reduce mortality, shortfin make sharks frequently interact with surface longline fisheries and the potential inability for fishermen to avoid the species may not lead to sufficient decreases in mortality. Therefore, the SCRS noted that other management measures, such as timearea closures, reduction of soak time, safe handling, and best release practices may also be required (ICCAT 2019).

In 2019, several countries presented proposals to end overfishing and rebuild the North Atlantic stock of shortfin mako shark; however, none were ultimately adopted (see Status Review Report for more detail). The United States, Senegal, Canada, the EU, and Morocco met several times to discuss the proposals, but were unable to reach agreement on the elements of a combined measure. In a proposal presented by the ICCAT Chair and adopted in 2019 (Recommendation 19-06), it was agreed to extend and update the existing provisions in Recommendation 17-08. Recommendation 19-06 also urged the Commission to adopt a new management recommendation for the North Atlantic shortfin make shark at its 2020 annual meeting in order to establish a rebuilding plan with a high probability of avoiding overfishing and rebuilding the stock to B_{MSY} within a timeframe that takes into account the biology of the stock. Due to the COVID-19 pandemic, however, ICCAT did not host an annual meeting in 2020 and management decisions were made through a correspondence process. Due to the difficulty associated with this process, no consensus could be made on a new measure and Recommendation 19-06 remained in place.

In 2021, the ICCAT annual meeting was conducted virtually and the conservation of the North Atlantic shortfin mako shark stock was a priority. Commission members reached consensus on Recommendation 21-09, which puts into place a 2-year retention ban that aims to reduce mortality and establishes a process to evaluate if and when retention may be allowed in the future, in line with scientific advice. The measure contains strong provisions to improve data reporting, and particularly, the catch reporting of live releases and fish discarded dead, by all ICCAT parties. This measure entered into force on June 17, 2022, and as data for each fishing year is not reported until the following calendar year, the management effect of Recommendation 21-09 will not be easily assessed until 2024 when the landings and discard data from 2023 can be analyzed. Despite this important step forward, ICCAT's work to end overfishing and rebuild North Atlantic shortfin make shark is not complete; within Recommendation 21–09 a provision exists to revisit the measure "no later than 2024 to consider additional measures to reduce total fishing mortality." Future efforts will likely be focused on reducing the athaulback and post-release mortality of North Atlantic shortfin make shark unintentionally captured alongside target species.

The low productivity of the shortfin mako shark means that the biological response to the recently adopted ICCAT measure will likely not be detectable for many years, despite assessment efforts. Therefore, at this time it is not possible to assess the adequacy of this measure to address the ongoing threat of overfishing in the North Atlantic. The ERA Team raised some concerns and uncertainties with regard to Recommendation 21-09. The measure does not require changes to fishing behavior or gear, and therefore will not address at-vessel or post-release mortality of incidentally caught shortfin mako sharks. Based on recent reported landings allowed under Recommendation 19–06 indicating high numbers of shortfin make sharks dead at-haulback, it is unclear if Recommendation 21–09 will reduce mortality to a point that will allow the North Atlantic stock to rebuild. It is also unclear what measures will be in place

after the 2-year period ends. The IATTC is responsible for the conservation and management of tuna and other pelagic species in the Eastern Pacific. There are currently no specific resolutions related to the management of shortfin make shark; however, IATTC does have resolutions relating to sharks

in general. Resolution C-16-05 on the management of shark species requires that purse-seine vessels promptly release any shark that is not retained as soon as it is seen in the net or on deck, and includes provisions for safe release of such sharks. Resolution C-05-03 requires that fins onboard vessels total no more than 5 percent of the weight of sharks onboard. The IATTC requires 100 percent observer coverage onboard the largest purse seine vessels, and 5 percent observer coverage on larger longline vessels.

The WCPFC is responsible for the conservation and management of highly migratory species in the Western and Central Pacific Ocean. The WCPFC aims to address issues related to the management of high seas fisheries resulting from unregulated fishing, overcapitalization, excessive fleet capacity, vessel re-flagging to escape controls, insufficiently selective gear, unreliable databases, and insufficient multilateral cooperation with respect to conservation and management of highly migratory fish stocks. There are currently no management measures specific to shortfin make sharks in the WCPFC; however, their management is addressed under the Conservation and Management Measure for Sharks (CMM 2019-04). This measure prohibits finning, requires that vessels land sharks with their fins naturally attached, and calls for vessels to reduce bycatch and practice safe release of sharks. In order to reduce bycatch mortality, the measure calls for longline fisheries targeting billfish and tuna to either not use wire branch lines or leaders, or not use shark lines (branch lines running directly off longline floats or drop lines). Further, the measure requires catches of key shark species to be reported to the Commission annually.

In Indian Ocean waters, the IOTC serves to promote cooperation among CPCs to ensure, through appropriate management, the conservation and optimum utilization of stocks, and encourage sustainable development of fisheries based on such stocks. The United States is not a member. Conservation and management measures are adopted in the form of either resolutions, which require a twothirds majority of Members present and voting to adopt them and are binding for contracting parties, or recommendations, which are nonbinding and rely on voluntary implementation. While a number of measures have been adopted by IOTC parties that apply to sharks and bycatch in general, there are currently no specific resolutions related to the management of shortfin make shark (see

IOTC 2019). In Resolution 15/01 on the recording of catch and effort by fishing vessels in the IOTC area of competence, all purse seine, longline, gillnet, pole and line, handline, and trolling fishing vessels are required to have a data recording system and provide aggregated data to the Secretariat each year. Resolution 15/02 mandates statistical reporting requirements for IOTC CPCs by species and gear for all species under the IOTC mandate as well as the most commonly caught elasmobranch species and lays out requirements for observer coverage. IOTC Resolution 17/05 on the conservation of sharks caught in association with fisheries managed by IOTC requires that sharks landed fresh not have their fins removed prior to first landing, and for sharks landed frozen, CPCs must abide by the 5 percent finsto-carcass weight ratio. Further, CPCs must report data for catches of sharks including all available historical data, estimates and life status of discards (dead or alive), and size frequencies under this resolution. Despite these requirements, reporting of shark catches has been very irregular and information on shark catch and bycatch is considered highly incomplete (Murua et al. 2018). A number of countries continue to not report on their interactions with bycatch species as evidenced by high rates of bycatch reported by other fleets using similar gear configurations (IOTC 2018). The lack of reliable records of catch and lack of a formal stock assessment make it difficult to determine whether the regulatory mechanisms described above are adequate to address overutilization of the species in the Indian Ocean.

Regarding the general shark conservation measures in place for WCPFC, IATTC, and IOTC, the ERA Team had concerns regarding low compliance with reporting requirements, especially in the Indian Ocean and South Atlantic Ocean. The lack of reliable catch data in these regions, as well as a lack of formal stock assessments in the Indian Ocean and South Pacific Ocean, make it difficult to assess whether regulatory mechanisms in these areas are adequate to address threats of overutilization to the species.

As the shortfin mako shark is highly valued for both its meat and fins, regulatory mechanisms ensuring that trade does not lead to overexploitation are critical to the species' survival. Many individual countries and RFMOs have implemented measures to curb the practice of shark finning and the sale of or trade in shark products over the last decade (see detailed information in the Status Review Report), and the shortfin

mako shark was listed on Appendix II of CITES as of November 2019. CITES is an international convention that aims to ensure that international trade in animals and plants does not threaten their survival, and while CITES regulates international trade, it does not regulate take or trade within a country. Appendix II includes species not necessarily threatened with extinction, but trade must be controlled to ensure utilization is compatible with their survival. As an Appendix II-listed species, international trade in specimens of shortfin make shark is allowed with an export permit, reexport certificate, or introduction from the sea certificate granted by the proper management authority. The above permits or certificates may be granted if the trade is found to be non-detrimental to the survival of the species in the wild and the specimen was found to have been legally acquired. A number of countries have taken a reservation to the listing (Botswana, Democratic Republic of the Congo, Eswatini, Japan, Namibia, Norway, South Africa, United Republic of Tanzania, Zambia, and Zimbabwe) meaning they have made a unilateral decision to not be bound by the provisions of CITES relating to trade in this species.

Although the CITES listing is a positive step to ensure the sustainability of the international trade of shortfin make sharks, it is difficult to assess the effectiveness of this measure over such a short period of time. An analysis of trade data and fin trimmings from a Hong Kong market led Cardeñosa et al. (2018) to conclude that compliance with reporting and permitting requirements for CITES-listed shark species listed at the 16th CITES Conference of the Parties (2013) was low in 2015–2016. Therefore, the CITES listing of shortfin mako shark may not have a strong impact on the number of individuals harvested for the international fin and meat trades. While the fin trade has declined, recent increases in the trade of shark meat signify the continued need for regulatory mechanisms to address the threat of overutilization in the international fin and meat trades.

Overall, while the ERA Team recognized the strong regulatory measures in place for shortfin mako sharks in U.S. domestic waters, retention bans that have been put in place for the species in several countries and recently by ICCAT, and increased global efforts to end shark finning, the ERA Team expressed concern about the adequacy of existing regulatory mechanisms to monitor and manage mortality from fisheries interactions on the high seas and the international meat

and fin trade. The ERA Team was split on how this factor contributes to the extinction risk of the species, with just over half of the group concluding that the inadequacy of existing regulatory mechanisms will likely contribute significantly to the species' risk of extinction in the foreseeable future as they defined it, but is not likely contributing to the species' extinction risk currently. The remaining members found it unlikely that this factor is significantly contributing to the species' extinction risk now or would do so in the foreseeable future as they defined it. We agree with the ERA Team's assessment that the inadequacy of existing regulatory mechanisms is not likely contributing to the species' risk of extinction currently. Over the foreseeable future of 50 years that we have determined is more appropriate to apply for this species, we find that existing regulatory mechanisms may be inadequate to address overutilization, especially given the species' low productivity and prevalence in both meat and fin markets.

Other Natural or Manmade Factors Affecting Its Continued Existence

Under this factor, the ERA Team considered potential threats posed by pollutants and environmental contaminants, climate change, and shark control/bather protection efforts.

As high-level predators, shortfin make sharks bioaccumulate and biomagnify heavy metals and organic contaminants; however, the impacts of these pollutants on the physiology and productivity of the species (and sharks in general) are poorly studied. While results of few available studies of other species of sharks and fish provide some evidence that sharks may experience negative physiological impacts and potentially reduced fitness as a result of contaminant exposure, the ERA Team found no evidence that individuals or populations are adversely affected to a degree that would impact the status of the species. Therefore, the ERA Team unanimously agreed that pollutants and environmental contaminants are unlikely to be contributing significantly to the species' extinction risk now or in the foreseeable future as they defined it. We agree that pollutants and environmental contaminants are not likely contributing significantly to the species' extinction risk now. Over the foreseeable future of 50 years that we have determined is more appropriate to apply for this species, we find that pollutants and environmental contaminants are not likely to significantly contribute to the shortfin mako shark's risk of extinction because

this factor is not currently negatively affecting the species' status and the best available scientific and commercial data suggests no basis to predict that this will change over the extended time horizon.

When considering the potential threat of climate change to the shortfin make shark, the ERA Team considered projected impacts to the marine environment (including warming waters, acidification, and shifting habitat suitability and prev distributions), and the species' potential responses to these impacts. While longterm climate projections (through 2100) are available and considered reliable, the ERA Team found that the species responses to these projected environmental changes that far into the future could not be predicted with any certainty. While some studies predict that the species may be subject to significant habitat loss and potential behavioral and fitness impairments by 2100, the shortfin make shark's broad prey base and thermal tolerance, among other factors, may give them a high adaptive capacity. A detailed review of available studies can be found in the Status Review Report. The majority of the ERA Team considered it unlikely that climate change is currently contributing to the species' extinction risk, or will contribute to the species' extinction risk in the foreseeable future as they defined it. Several ERA Team members concluded that the contribution of climate change to the extinction risk of the species in the foreseeable future could not be determined due to the lack of available information on the species' response to climate change. We agree that the best available scientific and commercial information indicates that climate change is not significantly contributing to the species' extinction risk now. Over the foreseeable future of 50 years that we have determined to be more appropriate to apply for this species, we also find that climate change is not likely to significantly contribute to the shortfin mako shark's risk of extinction because it is not currently negatively affecting the species' status and the best available scientific and commercial data suggests no basis to predict that this will change over the extended time horizon.

A small number of shortfin mako sharks experience mortality as a result of shark control/bather protection programs in South Africa and Australia, which aim to reduce the risk of shark attacks on humans near public beaches. Due to the localized geographic extent of the programs and the very low number of individuals impacted, the ERA Team did not find that shark control programs are likely contributing

to the extinction risk of the species now, and found it unlikely that these programs would contribute significantly to extinction risk in the foreseeable future as they defined it. We agree that the best available scientific and commercial information indicates that these programs are not likely contributing significantly to the species' extinction risk now. Over the foreseeable future of 50 years that we have determined to be more appropriate to apply for this species, we also find that bather protection nets are not likely to significantly contribute to the shortfin mako shark's risk of extinction because they are not currently negatively affecting the species' status and the best available scientific and commercial information suggests no basis to predict that this will change over the extended time horizon.

In sum, the ERA Team did not identify any other natural or manmade factors affecting the continued existence of the shortfin make shark, and we agree with their assessment.

Synergistic Impacts

We considered whether the impacts from threats described here and in the Status Review Report may cumulatively or synergistically affect the shortfin make shark beyond the scope of each individual stressor. As discussed previously, overutilization has resulted in historical declines across the species' range and is expected to continue to affect the species in certain regions over the foreseeable future. The impact of overutilization on the species increases when regulatory mechanisms to address this threat are inadequate. The species' low productivity means that it will take longer to rebuild a stock if it becomes depleted due to overutilization. While there is no evidence that range contractions have occurred, or that destruction or modification of shortfin mako shark habitat on a global scale has occurred to such a point that it has impacted the status of the species or is likely to in the foreseeable future, climate change has the potential to alter the distribution of prey species and suitable habitat that may result in changes in distribution. This may in turn impact the frequency of fisheries interactions and resulting fishing mortality. Further, climate changeinduced shifts in the marine food web have the potential to influence predation on juvenile shortfin mako sharks over the next several decades. We cannot reasonably predict either of these changes and their effects on the shortfin make shark based on the best available scientific and commercial information. While some studies project that the species may be subject to significant habitat loss by 2100, the shortfin mako shark's broad prey base and thermal tolerance, among other factors, may give them a high adaptive capacity (see the Status Review Report). The specific impacts that climate change will have on the species, and how the species might be able to adapt to changing oceanic conditions, is unknown. Therefore, while we considered these potential synergistic effects, we conclude that the best available scientific and commercial information indicates that climate change is not likely to act synergistically with other threats to increase the extinction risk of the shortfin make shark now or in the foreseeable future.

Extinction Risk Determination

Guided by the results and discussions from the demographic risk analysis and ESA Section 4(a)(1) factor assessment, the ERA Team analyzed the overall risk of extinction to the global shortfin mako shark population. In this process, the ERA Team considered the best available scientific and commercial information regarding the shortfin make shark from all regions of the species' global range, and analyzed the collective condition of these populations to assess the species' global extinction risk. The ERA Team was fairly confident in determining the overall extinction risk of the species, placing two-thirds of their likelihood points in the low risk category. Some uncertainty was reflected in the allocation of points to the moderate risk category, largely due to poor reporting of catches and low confidence in abundance and trends in certain regions. No points were allocated to the high risk category (see definitions of risk categories in *Methods*).

The ERA Team acknowledged that the shortfin mako shark has experienced historical declines of varying degrees in all ocean basins, mainly due to interactions with commercial fishing vessels, however, current abundance trends are mixed. A robust recent stock assessment in the North Pacific indicates that the species is stable and potentially increasing there, and population increases are also indicated in the South Pacific. In other words, across the entire Pacific Ocean basin, the species is either stable and/or potentially increasing. The recent stock assessment in the North Atlantic, which the ERA Team also considered highly reliable, indicates ongoing declines that will continue into the foreseeable future. However, the ERA Team concluded that this region is not at risk of extirpation based on available projections carried out by ICCAT's

SCRS, information on current fisheries mortality, and predictions about future management and levels of fisheries mortality. The South Atlantic may also have a declining population trend, but this is highly uncertain. Fisheries mortality remains high in the region. In the Indian Ocean, preliminary stock assessments indicate that the shortfin mako shark population is experiencing overfishing but is not overfished, and increasing CPUE trends are indicated in several key fisheries in this region. Compliance with reporting requirements is quite low in this region, however, so the ERA Team felt that the extent of the species' decline in this region is highly uncertain and potentially underestimated. Even with continued declines in the North Atlantic and likely population declines of uncertain degrees in the South Atlantic and Indian Oceans, the stable and potentially increasing population status in the Pacific Ocean, a major segment of the global population, led the majority of the ERA Team to conclude that abundance would not contribute significantly to the extinction risk of the species now or in the foreseeable future. The ERA Team also concluded that the shortfin mako shark's high genetic and ecological diversity, connectivity between populations, and wide spatial distribution reduce the species' extinction risk by providing resilience in the face of stochastic events and threats concentrated in certain regions. The ERA Team did, however, find that the low productivity of the species would likely contribute significantly to the species' risk of extinction in the foreseeable future as the species is highly susceptible to depletion from exploitation, and will recover slowly from such declines.

Overutilization in commercial fisheries and inadequate regulatory mechanisms to manage these fisheries are the main drivers of observed population declines. While regulatory mechanisms have recently been adopted to at least temporarily prohibit retention of the species in the North Atlantic and to ensure the sustainability of the international trade in shortfin mako shark products, it is too soon to accurately assess the adequacy of these measures to address overutilization. The ERA Team did consider the lack of compliance with reporting requirements in the Indian Ocean and South Atlantic Ocean concerning for the species, especially considering the high value of the species in the meat and fin trade. The low confidence in catch data also made it difficult for the ERA Team to assess whether regulatory mechanisms

are inadequate to address the threat of overutilization in these regions.

Overall, the ERA Team concluded that the species is not at high or moderate risk of extinction based on the following: (1) the high adaptability of the species based on its use of multiple habitat types, tolerance of a wide range of water temperatures, and generalist diet; (2) the existence of genetically and ecologically diverse, sufficiently wellconnected populations; (3) the species' wide spatial distribution with no indication of range contractions or extirpations in any region, even in areas where there is heavy bycatch mortality and utilization of the species' highvalue fins and meat; (4) the stable and potentially increasing population trend indicated in the Pacific Ocean, a major segment of the species' range; (5) abundance estimates of one million and eight million individuals in the North Atlantic and North Pacific, respectively; and (6) no indication that the species is experiencing depensatory processes due to low abundance. Based on all of the foregoing information, which represents the best scientific and commercial data available regarding current demographic risks and threats to the species, the ERA Team concluded that the shortfin currently has a low risk of extinction rangewide.

We agree with the ERA Team's assessment that the shortfin make shark is not at high risk of extinction rangewide for the above reasons. Extending the foreseeable future to 50 vears (two generation lengths), as we have determined is more appropriate to apply for this species, does not alter this conclusion and, for the reasons summarized here, we continue to find that the species is at low risk of extinction throughout its range. In the North Atlantic, the population is estimated to have experienced declines in total biomass of 47-60 percent and declines in SSF of 50 percent from 1950 to 2015 (ICCAT 2017). Since then, levels of fishing mortality in the North Atlantic have declined in response to management measures implemented in recent years (3,281 t in 2015; 3,356 t in 2016; 3,199 t in 2017; 2,373 t in 2018; 1,882 t in 2019; 1,709 t in 2020) (SCRS 2021). While we recognize that current levels of mortality (1,709 t in 2020) are higher than any of the TAC levels examined in the projections carried out by the SCRS (up to 1,100 t inclusive of dead discards, ICCAT 2019), over the next 50 years, recently adopted retention prohibitions and increasing international efforts to reduce the effects of fishing mortality on the species in this region will likely result in further decreases in fishing mortality in this

region (although we are unable to conclude the magnitude of potential declines, or whether they will be large enough to rebuild the stock). Therefore, the best available scientific and commercial information supports our forecast that the rate of decline will likely slow compared to the 1950-2015 time period. Although the stock is expected to decline until 2035 because the immature sharks that have been depleted in the past will age into the mature population over the next few decades, it is possible that the stock may be able to begin to rebuild if fishing mortality is low enough. Based on the above information, we find that future levels of total fishing mortality are not likely to lead to extirpation of the stock over the foreseeable future, even given estimates of historical and recent population decline. In the South Atlantic, the status of the shortfin make shark is currently unclear. While it is probable that the population is experiencing declines due to high fishing effort, current stock status is highly uncertain, and it is difficult to predict the magnitude of decline over the next 50 years. The South Pacific has an increasing trend and there is no indication that this will change over the next 50 years, although this trend is based on a shorter time period, introducing some uncertainty into the future status of the species in this region. In the North Pacific, the ISC Shark Working Group stock assessment (2018) indicates that spawning abundances are expected to increase gradually over a 10-year period (2017-2026) if fishing mortality remains constant or is moderately decreased relative to 2013-2015 levels. We take this to indicate that the current levels of fishing mortality in this region are allowing the population to grow, and there is no indication that this will change significantly in the foreseeable future. In the Indian Ocean, it is difficult to determine the stock status over the foreseeable future as current stock status is highly uncertain, with declines potentially underestimated due to poor reporting and data problems discussed above. The best available scientific and commercial information for the species in this region, including two preliminary stock assessments, indicates that the species is undergoing overfishing but is not overfished, and recent increasing CPUE trends are indicated in Spanish, Portuguese, and Taiwanese longline fleets. Thus, although there is significant uncertainty regarding the future status of this stock, and we acknowledge that declines have been indicated, we conclude that the

species is not at risk of extirpation in this region over the next 50 years. In sum, although fishing mortality remains high throughout the species' range and its low productivity life history does present a concern for the species' risk of extinction over the foreseeable future, we conclude on the basis of the best available scientific and commercial data that the rangewide species is neither currently in danger of extinction nor likely to become so within the foreseeable future.

Significant Portion of Its Range

Under the ESA and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so within the foreseeable future throughout all or a significant portion of its range. Having determined that the shortfin make shark is not in danger of extinction or likely to become so within the foreseeable future throughout all of its range, we now consider whether the shortfin mako shark is in danger of extinction or likely to become so within the foreseeable future in a significant portion of its range—that is, whether there is any portion of the species' range for which it is true that both (1) the portion is significant; and (2) the species, in that portion, is in danger of extinction or likely to become so within the foreseeable future. A joint USFWS-NMFS policy, finalized in 2014, provided the agencies' interpretation of this phrase ("SPR Policy," 79 FR 37578, July 1, 2014) and explains that, depending on the case, it might be more efficient for us to address the "significance" question or the "status" question first. Regardless of which question we choose to address first, if we reach a negative answer with respect to the first question, we do not need to evaluate the other question for that portion of the species' range.

We note that the definition of "significant" in the SPR Policy has been invalidated in two District Court cases that addressed listing decisions made by the USFWS. The SPR Policy set out a biologically-based definition that examined the contributions of the members in the portion to the species as a whole, and established a specific threshold (i.e., when the loss of the members in the portion would cause the overall species to become threatened or endangered). The courts invalidated the threshold component of the definition because it set too high a standard. Specifically, the courts held that, under the threshold in the policy, a species would never be listed based on the status of the species in the portion, because in order for a portion to meet

the threshold, the species would be threatened or endangered rangewide. Center for Biological Diversity, et al. v. Jewell, 248 F. Supp. 3d 946, 958 (D. Ariz. 2017); Desert Survivors v. DOI 321 F. Supp. 3d. 1011 (N.D. Cal., 2018). However, those courts did not take issue with the fundamental approach of evaluating significance in terms of the biological significance of a particular portion of the range to the overall species. NMFS did not rely on the definition of "significant" in the policy when making this 12-month finding. The ERA Team instead chose to first address the question of the species' status in portions of its range. While certain other aspects of the policy have also been addressed by courts, the policy framework and key elements remain in place, and until the policy is withdrawn we are bound to apply those aspects of it that remain valid.

Because there are infinite ways to divide up the species' range for an SPR analysis, the ERA Team only considered portions with a reasonable likelihood of being both in danger of extinction or likely to become so within the foreseeable future, and biologically significant to the species. In asking the "status" question first, the ERA Team considered whether the threats posed by overutilization and inadequate regulatory measures are geographically concentrated in any portion of the species' range at a biologically meaningful scale, or whether these threats are having a greater impact on the status of the species in any portions relative to other portions. While the shortfin make shark is subject to the threat of overutilization in commercial fisheries across its range, fishing mortality is substantially affecting the species in the North Atlantic Ocean, and is projected to continue impacting the species' status in this region over the next several decades. Because the North Atlantic stock of shortfin make shark is currently experiencing substantial negative effects of overfishing and inadequate regulatory mechanisms (i.e., declines in SSF of 50 percent from 1950 to 2015, as well as a 90 percent probability of being overfished and experiencing overfishing), and will continue to be impacted over the foreseeable future, the ERA Team concluded that there was a reasonable likelihood that the species is at greater risk of extinction in this portion relative to the remainder of the range and determined to proceed to consider whether in fact the individuals in that area were at moderate or high risk of extinction. The ERA Team also considered whether the Atlantic Ocean

as a whole is a portion that may be at risk of extinction now or in the foreseeable future based on indications of the species' decline in this portion, and to ensure a thorough analysis of the species' status in this ocean basin.

Separate from the ERA Team, we (NMFS) went on to consider whether other portions (the South Atlantic and the Indian Ocean) that were not explicitly considered by the ERA Team had a reasonable likelihood of being both in danger of extinction or likely to become so within the foreseeable future, and biologically significant to the species. In the South Atlantic, population declines of an unknown degree are likely occurring, and fishing mortality remains high. The best available scientific and commercial information indicates that the population has only a 19 percent probability of being overfished and experiencing overfishing, a 48 percent probability of not being overfished but overfishing occurring, or alternatively, being overfished but overfishing not occurring, and a 36 percent probability of not being overfished or experiencing overfishing (ICCAT 2017). The 2017 stock assessment of the population found conflicting results from different models, resulting in high uncertainty. However, the stock assessment notes that despite uncertainty, in recent years the stock may have been at, or is already below, B_{MSY}, and fishing mortality is already exceeding F_{MSY}. While the best available scientific and commercial information leads us to find that high levels of fishing mortality are likely leading to population declines in this region, there is no indication that the resulting decline reflects that the species in this portion has a reasonable likelihood of being in danger of extinction or likely to become so within the foreseeable future. Therefore, we did not consider the portion further. The best available scientific and commercial information indicates that the shortfin mako shark population in the Indian Ocean is considered to be experiencing overfishing but is not yet overfished, and recent CPUE increases have occurred in Spanish, Portuguese, and Taiwanese longline fleets. Although population declines are potentially underestimated due to poor reporting and data problems discussed previously, we do not have any indication that the preliminary stock assessments available for this region are invalid or suffer from methodological or other flaws that would lead us to discount them. As the stock is not considered overfished in either of these assessments, meaning that biomass has

not declined below the biomass at which the stock can produce maximum sustainable yield on a continuing basis, we find it unlikely that fishing mortality is impacting abundance to a degree that causes the species to be at risk of extinction or likely to become so in the foreseeable future in this portion of its range. Therefore, the best available information does not support a conclusion that the species has a reasonable likelihood of being at greater risk of extinction in this portion relative to the remainder of the range, and the Indian Ocean was not assessed further in the SPR analysis. Overutilization of the species does not appear to be occurring in the Pacific Ocean: the North Pacific population appears stable and is neither overfished nor experiencing overfishing based on robust data, and the South Pacific population has been indicated to be increasing with moderate certainty. There is no indication that any region in the Pacific has a reasonable likelihood of being in danger of extinction or likely to become so within the foreseeable future, and therefore no portions in the Pacific Ocean were considered further. The ERA Team therefore went on to assess the extinction risk of two portions: the North Atlantic Ocean and the Atlantic Ocean as a whole.

To determine extinction risk in each portion, the ERA Team used the likelihood point method as described previously in *Methods*. The ERA Team evaluated the best available information on the demographic threats and ESA Section 4(a)(1) factors for shortfin make sharks in each portion, beginning with the North Atlantic Ocean portion. The recent stock assessment conducted by ICCAT indicates that the North Atlantic shortfin mako shark has experienced declines in biomass of between 47-60 percent from 1950–2015, and predicts that SSF will continue to decline until 2035 regardless of fishing mortality levels. Despite the species' low productivity and the relatively high level of fishing mortality impacting the species, the ERA Team concluded that the species is not at high risk of extinction based on the current abundance of the species in the portion (estimated at one million individuals by FAO (2019)) and recent increased efforts to reduce fishing mortality that are likely to be effective, at least to some degree, in reducing the effect of overutilization on the species here. Many of the ERA Team's points were placed in the moderate risk category for the North Atlantic Ocean portion, which is reflective of the species low productivity and the considerable

uncertainty associated with potential effects of existing and future regulatory mechanisms aimed at rebuilding and ending overfishing of the North Atlantic shortfin make stock over the next few decades (i.e., whether or not the resulting reduction in fishing mortality is significant enough to end overfishing and begin to rebuild the species). However, the ERA Team placed the majority of its likelihood points in the low risk category and concluded that the North Atlantic portion has a low extinction risk. Despite its continuing declining trend, based on the best available scientific and commercial information, the ERA Team did not conclude that the rate of decline in the foreseeable future would be great enough to put the species in this portion at high risk of extinction in the foreseeable future (see the Status Review Report).

When conducting the analysis of the status of the species in the Atlantic Ocean as a whole, the ERA Team considered the highly uncertain fishing and abundance data available for the South Atlantic. Despite this uncertainty, the best available scientific and commercial data indicate that it is likely that the species' abundance in this region is declining, with ICCAT's SCRS finding a 19 percent probability that the stock is overfished and experiencing overfishing. The ERA Team also considered the possible effects of the retention prohibition in the North Atlantic and the potential for a shift in fishing effort for the species to the South Atlantic. Overall, the ERA Team found that the individuals of the species in the Atlantic Ocean portion as a whole were not at high risk of extinction based on available abundance and threats information. The ERA Team did place many points in the moderate risk category to reflect the species' low productivity, and the uncertainty in data and future regulatory mechanisms. However, the ERA Team placed the majority of its points in the low risk category because the level of fishing mortality and population decline expected within the foreseeable future does not place the species in this portion at high or moderate extinction risk in this timeframe.

Thus, to summarize, the ERA Team did not find the shortfin make shark to be in danger of extinction or likely to become so within the foreseeable future in either of these portions of its range. As a result, the ERA Team did not continue the analysis to evaluate whether either of these portions constitutes a biologically significant portion of the shortfin make shark's range.

We agree with the ERA Team's conclusions that the species is not in danger of extinction now within the North Atlantic or the Atlantic Ocean as a whole. When we extended the foreseeable future to 50 years, which we have determined is more appropriate to apply for this species, we also reached the same conclusion as the ERA Team. The North Atlantic shortfin make shark population is estimated to have experienced declines in total biomass of 47–60 percent and declines in SSF of 50 percent from 1950 to 2015 (ICCAT 2017). Since then, levels of fishing mortality in the North Atlantic have declined in response to management measures implemented in recent years (3,281 t in 2015; 3,356 t in 2016; 3,199 t in 2017; 2,373 t in 2018; 1,882 t in 2019; 1,709 t in 2020) (SCRS 2021). While we recognize that current levels of mortality (1,709 t in 2020) are higher than any of the TAC levels examined in the projections carried out by the SCRS (up to 1,100 t inclusive of dead discards, ICCAT 2019), over the next 50 years, recently adopted retention prohibitions and increasing international efforts to reduce the effects of fishing mortality on the species in this region will likely result in further decreasing levels of fishing mortality in this region (although we are unable to conclude the magnitude of potential declines, or whether they will be large enough to rebuild the stock). Therefore, the best available scientific and commercial information supports our forecast that the rate of decline will likely slow compared to the 1950–2015 time period. Although the stock is expected to decline until 2035 because the immature sharks that have been depleted in the past will age into the mature population over the next few decades, it is possible that the stock may be able to begin to rebuild if fishing mortality is low enough. We find that future levels of fishing mortality are not likely to place the species in danger of extinction in the foreseeable future within this portion, even given estimates of historical and recent decline. In the South Atlantic, it is likely that the population is experiencing decline of an unknown degree due to continued high fishing effort and mortality. Results of the 2017 stock assessment indicate a 19 percent probability that the stock is overfished and experiencing overfishing, with conflicting results from different models used. Current stock status is highly uncertain, and it is therefore difficult to predict the magnitude of decline over the next 50 years. However, the greater abundance, habitat area, spatial

distribution, and ecological diversity of the North and South Atlantic populations together as a portion provide additional resilience that makes extinction less likely. Therefore, we do not find that the Atlantic portion is likely to be in danger of extinction in the foreseeable future. Because we did not find the shortfin make shark to be in danger of extinction or likely to become so within the foreseeable future in either of these portions, and because to support a listing on the basis of SPR the individuals in a portion would need to both have a threatened or endangered status and be biologically significant to the overall species, we did not consider whether these portions qualify as significant portions of the shortfin make shark's range.

Distinct Population Segments

The petition to list the shortfin mako shark requested that NMFS list the species throughout its range, or alternatively, as DPSs, in the event that NMFS concludes that they exist. Therefore, we examined the best available information to determine whether DPSs may exist for this species. The petition did not provide information regarding potential DPSs of shortfin mako shark.

As discussed previously, the DPS Policy provides guidelines for defining DPSs and identifies two elements to consider in a decision regarding whether a population qualifies as a DPS: discreteness and significance of the population segment to the species (61 FR 4722; February 7, 1996). A population may be considered discrete if it is markedly separate from other populations of the same taxon as a consequence of physical, physiological, ecological, or behavioral factors, or if it is delimited by international governmental boundaries. Genetic differences between the population segments being considered may be used to evaluate discreteness. If a population segment is considered discrete, its biological and ecological significance must then be evaluated. Significance is evaluated in terms of the importance of the population segment to the overall welfare of the species. Some of the considerations that can be used to determine a discrete population segment's significance to the taxon as a whole include: (1) persistence of the population segment in an unusual or unique ecological setting; (2) evidence that loss of the population segment would result in a significant gap in the range of the taxon; and (3) evidence that the population segment differs markedly from other populations of the species in its genetic characteristics.

To determine whether any discrete populations of shortfin make sharks exist, we looked at available information on shortfin make shark population structure, including tagging, tracking, and genetic studies. As discussed previously in *Habitat Use* and *Population Structure and Genetics*, although certain ocean currents and features may limit movement patterns between different regions, available genetic studies indicate a globally panmictic population with some genetic structuring among ocean basins.

Heist et al. (1996) investigated genetic population structure using restriction fragment length polymorphism analysis of maternally inherited mtDNA from shortfin mako sharks in the North Atlantic, South Atlantic, North Pacific. and South Pacific. The North Atlantic samples showed significant isolation from other regions (p <0.001), and differed from other regions by the relative lack of rare and unique haplotypes, and high abundance of a single haplotype (Heist et al. 1996). Reanalysis of the data found significant differentiation between the South Atlantic and North Pacific samples (Schrey and Heist 2003) in addition to isolation of the North Atlantic.

A microsatellite analysis of samples from the North Atlantic, South Atlantic (Brazil), North Pacific, South Pacific, and Atlantic and Indian coasts of South Africa found very weak evidence of population structure ($F_{ST} = 0.0014$, P =0.1292; $R_{ST} = 0.0029$, P = 0.019) (Schrey and Heist 2003). These results were insufficient to reject the null hypothesis of a single genetic stock of shortfin mako shark, suggesting that there is sufficient movement of shortfin make sharks, and therefore gene flow, to reduce genetic differentiation between regions (Schrey and Heist 2003). The authors note that their findings conflict with the significant genetic structure revealed through mtDNA analysis by Heist et al. (1996). They suggest that as mtDNA is maternally inherited and nuclear DNA is inherited from both parents, population structure shown by mtDNA data could indicate that female shortfin mako sharks exhibit limited dispersal and philopatry to parturition sites, while male dispersal allows for gene flow that would explain the results from the microsatellite data (Schrey and Heist 2003).

Taguchi et al. (2011) analyzed mtDNA samples from the North and South Pacific, North Atlantic, and Indian Oceans, finding evidence of significant differentiation between the North Atlantic and the Central North Pacific and Eastern South Pacific (pairwise Φ_{ST} = 0.2526 and 0.3237, respectively).

Interestingly, significant structure was found between the eastern Indian Ocean and the Pacific Ocean samples (pairwise Φ_{ST} values for Central North Pacific, Western South Pacific, Eastern South Pacific are 0.2748, 0.1401, and 0.3721, respectively), but not between the eastern Indian and the North Atlantic.

Corrigan et al. (2018) also found evidence of matrilineal structure from mtDNA data, while nuclear DNA data provide support for a globally panmictic population. Although there was no evidence of haplotype partitioning by region and most haplotypes were found across many (sometimes disparate) locations, Northern Hemisphere sampling locations were significantly differentiated from all other samples, suggesting reduced matrilineal gene flow across the equator (Corrigan et al. 2018). The only significant differentiation indicated by microsatellite data was between South Africa and southern Australia (pairwise $F_{ST} = 0.037$, $\Phi_{ST} = 0.043$) (Corrigan *et al.* 2018). Clustering analysis showed only minor differences in allele frequencies across regions, and little evidence of population structure (Corrigan et al. 2018). Overall, the authors conclude that although spatial partitioning exists, the shortfin make shark is genetically homogenous at a large geographic scale.

Taken together, results of genetic analyses suggest that female shortfin mako sharks exhibit fidelity to ocean basins, possibly to utilize familiar pupping and rearing grounds, while males move across the world's oceans and mate with females from various basins (Heist et al. 1996; Schrey and Heist 2003; Taguchi et al. 2011; Corrigan et al. 2018). This finding does not support the existence of discrete population segments of shortfin mako sharks.

We also considered whether available tracking data support the existence of discrete population segments of shortfin mako shark. There is some evidence that certain ocean currents and features may limit movement patterns, including the Mid-Atlantic ridge separating the western and eastern North Atlantic, and the Gulf Stream separating the North Atlantic and the Gulf of Mexico/ Caribbean Sea (Casey and Kohler 1992; Vaudo et al. 2017; Santos et al. 2020). However, conventional tagging data indicates that movement does occur across these features (Kohler and Turner 2019). In the Pacific, tagging data supports east-west mixing in the north and minimal east-west mixing in the south (Sippel et al. 2016; Corrigan et al. 2018). Trans-equatorial movement may be uncommon based on some tagging studies, though tagged shortfin mako

sharks have been recorded crossing the equator (Sippel *et al.* 2016; Corrigan *et al.* 2018; Santos *et al.* 2021). Therefore, we conclude that there do not appear to be major barriers to the species' dispersal that would result in marked separation between populations.

Overall, we find that the best available scientific and commercial information does not support the existence of discrete populations of shortfin make shark. Because both standards, of discreteness and significance, have to be met in order to conclude that a population would constitute a DPS, we conclude that there are no population segments of the shortfin make shark that would qualify as a DPS under the DPS Policy.

Final Listing Determination

Section 4(b)(1) of the ESA requires that NMFS make listing determinations based solely on the best scientific and commercial data available after conducting a review of the status of the species and taking into account those efforts, if any, being made by any state or foreign nation, or political subdivisions thereof, to protect and conserve the species. We relied on available literature and information from relevant countries to evaluate efforts to protect and conserve the species, including National Plans of Action for the Conservation and Management of Sharks (NPOA-Sharks), which are developed under the IPOA-SHARKS and aim to ensure the conservation, management, and longterm sustainable use of sharks. While the development of NPOAs provide some indication of the level of commitment of a catching country to manage its shark fisheries and provides a benefit to sharks, the quality of existing NPOA-Sharks varies, and there are no reporting mechanisms on implementation of the NPOAs; thus, it remains uncertain whether a particular plan is being implemented or what impact the plan has had on conservation and management of sharks. These conservation efforts do not change the conclusion we would otherwise have reached regarding the species' status. We have independently reviewed the best available scientific and commercial information, including the petitions, public comments submitted in response to the 90-day finding (86 FR 19863; April 15, 2021), the Status Review Report, and other published and unpublished information. We considered each of the statutory factors to determine whether each contributed significantly to the extinction risk of the species. As required by the ESA, section 4(b)(1)(a), we also took into account

efforts to protect shortfin mako sharks by states, foreign nations, or political subdivisions thereof, and evaluated whether those efforts provide a conservation benefit to the species. As previously explained, we could not identify a significant portion of the species' range that is threatened or endangered, nor did we find that any DPSs of the species exist. Therefore, our determination is based on a synthesis and integration of the foregoing information, factors and considerations, and their effects on the status of the species throughout its entire range.

We have determined the shortfin mako shark is not presently in danger of extinction, nor is it likely to become so in the foreseeable future throughout all or a significant portion of its range. This finding is consistent with the statute's requirement to base our findings on the best scientific and commercial data available, summarized and analyzed above. Therefore, the shortfin mako shark does not meet the definition of a threatened species or an endangered

species and does not warrant listing as threatened or endangered at this time.

This is a final action, and, therefore, we are not soliciting public comments.

References

A complete list of the references used in this 12-month finding is available online (see ADDRESSES) and upon request (see FOR FURTHER INFORMATION CONTACT).

Peer Review

In December 2004, the Office of Management and Budget (OMB) issued a Final Information Quality Bulletin for Peer Review establishing minimum peer review standards, a transparent process for public disclosure of peer review planning, and opportunities for public participation. The OMB Bulletin, implemented under the Information Quality Act (Pub. L. 106–554) is intended to enhance the quality and credibility of the Federal Government's scientific information, and applies to influential or highly influential scientific information disseminated on

or after June 16, 2005. To satisfy our requirements under the OMB Bulletin, we obtained independent peer review of the Status Review Report. Three independent specialists were selected from the academic and scientific community for this review. All peer reviewer comments were addressed prior to dissemination of the final Status Review Report and publication of this 12-month finding. The Peer Review Report can be found online at: https:// www.noaa.gov/information-technology/ endangered-species-act-status-reviewreport-shortfin-mako-shark-isurusoxvrinchus-id430.

Authority: The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 et seq.).

Dated: November 4, 2022.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

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Part III

Department of Homeland Security

Coast Guard

46 Parts 121, 160, et al.

Survival Craft Equipment—Update to Type Approval Requirements; Final Rule

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Parts 121, 160, 169, 184, and 199

[Docket No. USCG-2020-0107]

RIN 1625-AC51

Survival Craft Equipment—Update to Type Approval Requirements

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Final rule.

SUMMARY: The Coast Guard is updating the type approval requirements for certain types of equipment that survival craft are required to carry on U.S.-flagged vessels. This rule will remove Coast Guard type approval requirements for nine of these types of survival craft equipment and replace them with the requirement that the manufacturer self-certify that the equipment complies with a consensus standard.

DATES: This final rule is effective December 14, 2022.

The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register on December 14, 2022. The incorporation by reference of certain other publications listed in the rule were approved by the Director of the Federal Register on October 1, 1996.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to https://www.regulations.gov, type USCG—2020—0107 in the search box and click "Search." Next, in the Document Type column, select "Supporting & Related Material."

FOR FURTHER INFORMATION CONTACT: For information about this document, call or email Ms. Stephanie Groleau, Lifesaving & Fire Safety Division (CG–ENG–4), Coast Guard; telephone 202–372–1381, email Stephanie.M.Groleau@uscg.mil.

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I. Abbreviations

ASTM ASTM, International BLS U.S. Bureau of Labor Statistics CFR Code of Federal Regulations CG–ENG–4 Office of Design and Engineering Standards, Lifesaving & Fire Safety Division

CGMIX U.S. Coast Guard Maritime Information Exchange

COA Certificate of approval

DHS Department of Homeland Security ECEC Employer Costs for Employee Compensation

FDA U.S. Food and Drug Administration FR Federal Register

IBA Inflatable buoyant apparatus
IBC Code International Code for the
Construction and Equipment of Ships
Carrying Dangerous Chemicals in Bulk

IGC Čode Amendments to the International
 Code for the Construction and Equipment
 of Ships Carrying Liquefied Gases in Bulk
 ICR Information collection request
 IMO International Maritime Organization

ISO International Organization for Standardization

LSA Code Life-Saving Appliances Code MISLE Marine Information for Safety and Law Enforcement

NAICS North American Industry Classification System

NPRM Notice of proposed rulemaking OES U.S. Bureau of Labor Statistics

Occupational Employment Statistics
OMB Office of Management and Budget
OPM Office of Personnel Management
OTC Over-the-counter

RA Regulatory analysis SOLAS International Convention for the Safety of Life at Sea

§ Section

U.S.C. United States Code

II. Basis, Purpose, and Regulatory History

The legal authority for this rule is found in Title 46 of the United States Code (U.S.C.) Sections 2103, 3103, 3306, 3703, 4102, 4302, 4502, 7101, and 8101. The Secretary of the Department of Homeland Security (DHS) has delegated these statutory authorities to the Coast Guard pursuant to 14 U.S.C. 502 through DHS Delegation No. 00170.1, Revision No. 01.2, paragraph (II)(92)(a), (b), (e), and (f). Additionally, 14 U.S.C. 102(3) grants the Coast Guard broad authority to promulgate and enforce regulations for the promotion of safety of life and property on waters subject to the jurisdiction of the United States.

The purpose of this rule is to update the type approval requirements for 12 types of survival craft equipment that survival craft are required to carry on

certain, specified U.S.-flagged vesselsbilge pumps, compasses, fire extinguishers, first-aid kits, fishing kits, hatchets, jackknives, knives, signaling mirrors, provisions (food rations), emergency drinking water, and sea anchors—as well as some of the survival craft equipment required for sailing school vessels. For nine of these types of equipment, this rule will replace the Coast Guard type approval requirement with a requirement that the manufacturer self-certify that the equipment complies with a consensus standard: bilge pumps, compasses, firstaid kits, fishing kits, hatchets, jackknives, mirrors, sea anchors, and water. Type approval is the primary process for equipment and materials to receive Coast Guard approval. Updating type approval requirements for survival craft equipment will result in cost savings to equipment manufacturers, vessel owners and operators, and the Coast Guard.

The Coast Guard issued a notice of proposed rulemaking (NPRM) on October 5, 2020, and solicited public comment on the proposal during a comment period of 60 days. The comment period closed on December 4, 2020. The Coast Guard received 13 comment submissions, which are discussed later in this document.

III. Background

Many of the current requirements for survival craft equipment were developed in the 1950s and 1960s and have not been significantly updated since they were published. After thorough review of these requirements, as well as Coast Guard enforcement procedures, current maritime industry practice, and the availability of new consensus standards, we believe that the additional scrutiny provided by Coast Guard type approval does not increase the safety of the following nine types of survival craft equipment: bilge pumps, compasses, first-aid kits,2 fishing kits, hatchets, knives (including jackknives), mirrors, sea anchors, and emergency drinking water.

For these types of equipment, the current Coast Guard type approval requirements are outdated and overly prescriptive. This places a burden on the equipment manufacturers, which, in turn, affects the design costs of complying with the outdated standard, the administrative overhead costs, and the time-to-market costs of manufacturing and selling equipment.

¹ 85 FR 62842.

² Different first-aid kits are required for different survival craft, and this is explained in section IV of this rule under *First-Aid Kits*.

The requirements also place a financial burden on the vessel owners and operators who are required to carry this specific approved equipment on board their survival craft. This equipment is frequently more costly and more difficult to obtain than similar products that are not type-approved. Finally, the requirements place a burden on the Coast Guard to review and approve this equipment without commensurate increases in safety.

IV. Discussion of Comments

The Coast Guard received 13 comment submissions in response to the NPRM. Of those 13 comments, 1 was a duplicate and 1 was unrelated to the rulemaking. The remaining 11 comments were from maritime organizations, private companies, and individuals. Four comments we classified as general comments, two comments concerned technical standards, and five comments concerned first-aid kits. Below, we discuss each comment and our responses.

General

The Coast Guard received four comments on the NPRM that we categorized as general comments. One comment supported the proposed regulatory changes for approval requirements for first-aid kits. The Coast Guard acknowledges this comment.

Two commenters expressed concerns that removing type approval requirements could decrease the quality of survival craft equipment. We disagree. Even without a type approval requirement, the following checks will remain in place. For emergency drinking water in survival craft and rescue boats, the water quality will be verified by the local municipality or by an independent laboratory accepted by the Coast Guard, as required by 46 CFR 199.175(b)(40). Coast Guard-approved liferaft servicing facilities inspect survival equipment packed in inflatable liferafts prior to packing. Coast Guard marine inspectors also regularly check equipment not packed in inflatable liferafts, such as that in a lifeboat or rescue boat, or the first-aid kits carried on small passenger vessels, when conducting the required inspections on board commercial vessels.

Additionally, one commenter, a manufacturer of the approved Coast Guard items, expressed multiple concerns regarding this rule and the Coast Guard's regulatory analysis on its estimate of the impacts in the NPRM. This commenter said that removing type approval requirements will cause the market to be flooded with substandard

products, leading to revenue losses to the company. The commenter also said that the liferaft and lifeboat industry has consolidated and there is little competition, and, therefore, will not pass savings on to consumers.

For the reasons explained in our response to the two commenters above, we do not expect reduced quality in the equipment that is no longer required to be type-approved. We therefore do not expect a flood of products of reduced quality that drive down prices. With this final rule, prescriptive requirements will be replaced by consensus standards. Conforming to these international consensus standards will maintain the same level of safety without imposing unnecessary burdens on the public and provide alternatives for compliance. These compliance alternatives should result in cost savings to the directly impacted entities, which are manufacturers and vessel owners and operators. The Coast Guard does not have adequate industry information or data to estimate secondary impacts and indicate whether these savings will be passed on to the final consumers or end users of services provided by vessel owners and operators.

The commenter also suggested that some could incur additional testing costs as a result of this rule. Based on a review of the new and existing standards, the Coast Guard has not found that manufacturing firms will have new testing requirements under the International Organization for Standardization (ISO) standards.

The commenter suggested that, as an alternative to the removal of type approval requirements, the manufacturer could cover the cost of the certificate of approval (COA). Requiring manufacturers to cover the cost of the COA would result in additional costs to manufacturers without any attendant safety benefits.

Finally, the commenter asserted that our per-device savings estimates are too high and not the going rates in the industry. In preparing our economic analysis, we relied primarily on websites listing the retail prices of different products that were sold under ISO standards instead of Coast Guard standards. We believe that the reason our prices appear to be high to the commenter is because our analysis was based on retail prices rather than wholesale prices, or the prices that manufacturers use to sell their products to businesses. Using retail prices is a common approach across Coast Guard rulemaking, because we do not have access to consistent wholesale price data across the industry.

F1003 and F1014 Standards

The Coast Guard received two comments recommending incorporation of ASTM F1003 (2019), "Standard Specification for Searchlights on Motor Lifeboats," and ASTM F1014 (2020), "Standard Specification for Flashlights on Vessels." These 2019 and 2020 standards are more recent editions of the ASTM standards we proposed to adopt.

However, these standards were updated after the NPRM was developed, and so we were unable to include them in our proposed rule. The more recent standards contain significant differences as compared to the prior editions (the ones we incorporate in this rule), such that more evaluation is necessary. We will consider incorporating these standards in a future rulemaking.

First-Aid Kits

The Coast Guard received five comments concerning the proposed changes to first-aid kits. The comments discussed contents of the first-aid kits, as well as technical standards that apply to first-aid kits.

Two commenters supported the proposed use of commercially available first-aid kits, to remove the burden of assembling very specific kit components.

Three commenters called for specified first-aid kit components, rather than leaving the exact number and size of items up to manufacturers so long as the kit meets ISO 18813:2006. These commenters said the kit contents should be standardized, and expressed concern that manufacturers would not provide adequate kits. One commenter also said that ISO 18813:2006 is not a widely accepted standard and may soon be revised; that commenter suggested the Coast Guard should develop its own standard instead. Another commenter supported the use of the ISO standard. We believe that the contents described in ISO 18813:2006 are sufficient to meet the needs of basic first-aid kits required by mariners in a survival situation. The ISO standard specifies design, performance, and use of various items of survival equipment carried in survival craft and rescue boats complying with the International Convention for the Safety of Life at Sea (SOLAS), 1974 (as amended), and the International Maritime Organization (IMO) Life-Saving Appliance Code (LSA Code). The 2006 edition is the most current version of this standard that is available at this

During periodic shipboard inspections by both Coast Guardlicensed mariners and Coast Guard marine inspectors, first-aid kits not packed in inflatable liferafts are examined to ensure that they contain all the items listed in the provided instructions, that each unit carton is in an intact waterproof package, and that they meet the applicable regulatory requirements. First-aid kits packed in inflatable liferafts are inspected by Coast Guard-approved liferaft servicing facilities, also to ensure that they contain all the required items.

One commenter specifically called for a particular Coast Guard-approved watertight soft plastic pouch to contain the first-aid kit, because rigid plastic containers can become brittle and because that pouch is proven to meet the applicable durability requirements. ISO 18813:2006 discourages the use of rigid plastic cases that can shatter. If the case shatters, an entirely new kit must be purchased because it is in a not-asapproved condition, and Coast Guard inspectors would give the vessel a deficiency for not having an approved and in-working-condition piece of equipment. This would increase costs to the vessel.

One commenter noted that the U.S. Food and Drug Administration (FDA) does not routinely approve over-the-counter (OTC) products; it only reviews active ingredients. Another comment inquired about the FDA regulatory status, product form, or type of delivery for two topical preparations in the ISO 18813 requirements.

It is up to the first-aid kit manufacturer to determine in what form the medicinal products are to be provided to meet the intended needs of the first-aid kit. However, medicinal products must meet the applicable OTC drug requirements outlined in title 21 of the Code of Federal Regulations (CFR) part 330, which contains FDA's applicable OTC requirements. In response to these comments, in this rule we revised the regulatory text of § 199.175(b)(10)(ii) to reference 21 CFR part 330.

One commenter asked that the Coast Guard remove the requirement for specific items with an expiration date (such as aspirin) and allow for equivalent alternatives. The commenter said that getting supplies delivered to remote locations can be challenging. The expiration date of OTC medications is typically between one and five years after manufacture. The commenter did not specify an alternative item without an expiration date, but the Coast Guard believes that a year or more is a reasonable period to plan for replacing first-aid supplies. In general, the Coast Guard believes that expiration dates are acceptable and can help ensure that the

first-aid kit is reviewed and refreshed at intervals. The Food and Drug Administration requires OTC medications have expiration dates (see 21 CFR 211.137 and 211.166).

The same commenter recommended that vessel operators be allowed to exclude analgesics (pain relief medication) from first-aid kits. This commenter said that companies often prohibit their vessel crew members from giving out analgesic medication because of possible adverse side effects or interactions with other medication. In support of this recommendation, the commenter said that most passenger vessels operate near shore with easy access to shoreside medical services.

While access to shoreside medical resources may be available in certain areas of operation, these should not be relied on to provide the required first-aid supplies. Shoreside medical resources will not be readily available to someone with an injury or emergency on the vessel. The first-aid kit for survival craft is intended to be used in an emergency away from shore.

Licensed mariners operating vessels in commercial service are required to have basic first-aid training. Any application of first aid should be given at the discretion of the licensed mariner and not at a level beyond the training or capability of the mariner administering the first aid. Analgesics are common OTC medications that do not require medical supervision, and the decision to take them is up to the person who requests them. Accordingly, the Coast Guard has decided to retain the requirement for analgesics in first-aid kits.

V. Discussion of Final Rule and Changes From NPRM

This final rule amends several approval and carriage requirements in title 46 CFR. Specifically, this final rule updates the requirements in part 199, subchapter W, related to the equipment on survival craft and rescue boats on inspected vessels by replacing the requirement to carry Coast Guardapproved equipment with selfcertification to voluntary consensus standards for certain equipment. This rule also makes conforming changes to part 169, subchapter R, for sailing school vessels that are not covered by subchapter W. In addition, this final rule revises part 160, subchapter Q, to remove approval standards for the survival craft equipment that is no longer required to be approved by the Coast Guard, and it updates the requirements for approval of emergency provisions to replace prescriptive Coast Guard requirements with consensus

standards. A new subpart 160.046, Emergency Provisions, is added, to consolidate the applicable standards. Finally, this rule removes the requirement in part 121, subchapter K, and part 184, subchapter T, that first-aid kits carried on small passenger vessels must be approved by the Coast Guard, and updates those requirements to consensus standards to align with the revised approval requirements.

This final rule includes incorporation by reference of several voluntary consensus standards consistent with the National Technology Transfer and Advancement Act of 1995, Public Law 104-113 (codified as a note to 15 U.S.C. 272). Three of the consensus standards this rule incorporates are international standards: ISO 18813:2006, "Ships and marine technology—Survival equipment for survival craft and rescue boats' (referred to as ISO 18813); ISO 17339:2018, "Ships and marine technology—Sea anchors for survival craft and rescue boats" (referred to as ISO 17339); and ISO 25862:2009, "Ships and marine technology-Marine magnetic compasses, binnacles and azimuth reading devices" (referred to as ISO 25862).

While the IMO does specify some standards for survival craft equipment affected by this rule, it does not stipulate that the affected survival craft equipment be approved by the Administration. In some cases (such as first-aid kits and drinking water), the LSA Code references ISO 18813 as an acceptable standard for the equipment to meet, whereas in others (such as fishing tackle), the LSA Code merely requires that the equipment be carried aboard the specified survival craft.

A more detailed explanation of the amendments to the aforementioned sections can be found in the NPRM. A number of non-substantive changes from the NPRM are made with this final rule to correct typographical, grammar, and format errors or issues, as well as for clarification purposes.

Lastly, as a result of public comment, this final rule requires that medicinal products meet the applicable OTC drug requirements as outlined in 21 CFR part 330. This administrative change is simply updating an improper reference.

VI. Incorporation by Reference

Material incorporated by reference is currently listed in 46 CFR 199.05 and is added to the new § 160.046–3. Under 5 U.S.C. 552(a) and 1 CFR part 51, a publication is eligible for incorporation by reference if it meets Office of the Federal Register policies and is reasonably available to and usable by the class of persons affected.

Regulations in part 51 require that agencies discuss, in the final rule, ways that the materials the agency incorporates by reference are reasonably available, to interested parties and how interested parties can obtain the materials. In addition, the preamble to the final rule must summarize the material.

In accordance with the OFR's requirements, section VII.L. of this final rule summarizes the standards that the Coast Guard incorporates by reference in §§ 160.046–3 and 199.05. Interested persons have access to this material through their normal course of business, may purchase it from the organization, or may view a copy at Coast Guard Headquarters.

VII. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below, we summarize our analyses based on these statutes or Executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

The Office of Management and Budget (OMB) has not designated this rule a significant regulatory action under

section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it. A regulatory analysis (RA) follows.

The Coast Guard received several public comments on the NPRM, as discussed in section IV. of the preamble to this final rule. In response to a comment, in this final rule we are making an editorial change to 46 CFR 199.175(b)(10) that has no cost impact. See table 1.

Additionally, we are replacing prescriptive requirements with international standards that provide alternatives for compliance, which should result in cost savings to impacted entities. We also made some changes to the regulatory analysis, including updating the population of affected entities, and the wage rate using 2020 estimates, and removing the renewal instruction, because it is not applicable to this rule.

TABLE 1—CHANGES FROM NPRM TO FINAL RULE

Section	Description of change	Explanation	Cost impact of change
§ 199.175(b)(10)	Editorial change that corrects a reference.	Update the language to correctly discuss the FDA's drug approval process.	No impact because it is up- dating an improper ref- erence.

With this final rule, the Coast Guard removes the requirement for nine types of survival craft equipment to be approved by the Coast Guard from 46 CFR part 160 in subchapter Q (Equipment, Construction, and Materials: Specifications and Approval) and from § 199.175 (Survival Craft and Rescue Boat Equipment). The requirement for approvals on these nine types of equipment (bilge pumps, compasses, first-aid kits, fishing kits, hatchets, jackknives, mirrors, sea anchors, and water) will be replaced by a self-certification requirement, in order to comply with the LSA Code. For those types of equipment that still require a COA, we do not estimate any changes in costs or cost savings.³ Finally, this rule updates the survival craft requirements for sailing school vessels found in §§ 169.525 through 169.529, eliminating the unique requirements for survival craft equipment on these vessels.

Table 2 provides a summary of the affected population, costs, cost savings, and benefits of this rule. The affected population includes the manufacturers of survival craft equipment and the vessels equipped with survival craft. We estimate the cost savings to manufacturers by reducing reporting,

recordkeeping, and production requirements of this survival craft equipment. We estimate the cost savings to vessel owners and operators by the price reductions in survival craft equipment, and we estimate the cost savings for the Government for reducing the review necessary for certain equipment. We estimate an annualized cost savings to industry of \$303,805 (with a 7-percent discount rate) and an annualized cost savings to the Government of \$10,087, for a total annualized cost savings of \$313,892.4

TABLE 2—SUMMARY OF THE AFFECTED POPULATION, COSTS, COST SAVINGS, AND BENEFITS

Category	Summary
Applicability	Revises the approval requirements specific to nine types of survival craft equipment by removing the Coast Guard type approval requirements and, instead, adopting a voluntary consensus standard, ISO 18813, "Ships and marine technology—Survival equipment for survival craft and rescue boats." Also retains requirements for Coast Guard approval of emergency provisions, but revises the requirements to refer to ISO 18813 instead of prescriptive Coast Guard regulations.
Affected Population	Includes 16 manufacturers of 28 unique Coast Guard-approved products for 9 types of equipment; 14,747 existing U.Sflagged vessels with 31,729 survival craft; and 113 new U.Sflagged vessels annually with 449 survival craft.
Costs	There will be no costs to industry or the Federal Government as this rule will reduce the burden(s).
Benefits	There are non-monetary benefits to owners and operators of vessels with survival craft in having a larger selection of equipment to choose from, allowing for potential operational flexibility.
Industry Cost Savings *	Annualized: -\$303,805, 10-Year: -\$2.13 million.

³ Knives are not required to be Coast Guardapproved; however, they must meet the requirements in Section 4.1.5.1.2 of the LSA Code.

This is an administrative change that will lead to no cost or cost savings.

⁴ This analysis assumes the implementation year for this rule will be 2021

TABLE 2—SUMMARY OF THE AFFECTED POPULATION, COSTS, COST SAVINGS, AND BENEFITS—Continued

Category	Summary
	Annualized: -\$10,087, 10-Year: -\$70,847. Annualized: -\$313,892, 10-Year: -\$2.20 million.

^{*}The Industry Cost Savings, Government Cost Savings, and Total Cost Savings are all discounted at 7 percent.

Affected Population

This rule impacts three separate affected populations. First, this rule impacts manufacturers of Coast Guardapproved equipment because it changes the standards and approval process for nine types of survival craft equipment. Second, this rule impacts any new and existing U.S.-flagged vessels that carry survival craft because it will reduce the cost of buying and replacing survival craft equipment. Third, this rule impacts small passenger vessels inspected under subchapter K or T. They are required to maintain a separate first-aid kit stowed on board, and this rule reduces the cost of replacing firstaid kits. This rule also removes Table 169.527 from part 169 and removes the requirements for equipment outlined in § 169.529(a) through (mm) to conform to the changes made in 46 CFR part 199.

Data on manufacturers comes from the U.S. Coast Guard Maritime Information Exchange (CGMIX),⁵ which is a public-facing version of the Marine Information for Safety and Law Enforcement (MISLE) database, unless otherwise specified. For each subchapter of inspected vessels that are required to carry survival craft, we used the MISLE database to estimate the number of vessels that will be affected by this rule.

Manufacturers of Coast Guard Approved Equipment

The Coast Guard is eliminating approval requirements for nine types of survival craft equipment, discussed in detail in section V of this rule. These nine types of equipment include: (1) bilge pumps, (2) compasses, (3) first-aid kits for lifeboats and for liferafts, (4) fishing kits, (5) hatchets, (6) jackknives, (7) signaling mirrors, (8) sea anchors, and (9) emergency drinking water. For these 9 types of survival equipment, there are 28 unique Coast Guard typeapproved products.⁶ This rule impacts manufacturers of products currently on the market as well as newly approved products. Currently approved products in use on survival craft will remain acceptable for the purpose of carriage after this rule's implementation.

The 2019 information collection request (ICR) "Supporting Statement for

Title 46 CFR Subchapter Q: Lifesaving, Electrical, Engineering and Navigation Equipment, Construction and Materials & Marine Sanitation Devices (33 CFR part 159)" (OMB Control Number: 1625–0035) estimates that companies will seek Coast Guard approval for 3 percent of the number of survival craft equipment product types on the market each year. The Coast Guard estimates that each new product approval replaces a preexisting product approval, such that the total number of approved products will not change each year, as the number of newly approved products has historically been small.

Table 3 presents the annual average of new products each year for the nine types of survival craft equipment. To calculate the annual average of new products, we multiplied the values in the "Number of Approved Products" column (a), which contains the number of existing approved products for each type of survival craft equipment, by 3 percent, from the "Percentage of New Approvals Each Year" column, (b).

TABLE 3—Number of Products Currently Approved by the Coast Guard

Equipment	Approval series	Number of approved products *	Percentage of new approvals each year **	Annual average number of new products each year
		(a)	(b)	$(c) = (a) \times (b)$
Bilge pump	160.044	3	3	0.09
Bilge pump Compass	160.014	3	3	0.09
First-aid kit for Lifeboats	160.041	5	3	0.15
First-aid kit for Liferafts	160.054	5	3	0.15
Fishing kit	160.061	1	3	0.03
Hatchet	160.013	1	3	0.03
Jackknife	160.043	1	3	0.03
Mirror, Signalling	160.020	2	3	0.06
Sea anchor	160.019	1	3	0.03
Water	160.026	6	3	0.18
Total		28		1

Sources:

** "Supporting Statement for Title 46 CFR Subchapter Q: Lifesaving, Electrical, Engineering and Navigation Equipment, Construction and Materials & Marine Sanitation Devices (33 CFR 159)" (OMB Control Number: 1625–0035).

Note: Values may not sum due to rounding.

^{*} CGMIX data pull, March 2021.

⁵ https://cgmix.uscg.mil/.

⁶ Type Approval is the primary process for equipment and materials to receive Coast Guard

U.S.-Flagged Vessels That Carry Coast Guard-Approved Equipment

This rule impacts a total of 14,747 existing vessels. These vessels, which are categorized by subchapter, are

required to carry survival craft in accordance with the applicable regulations. Of these vessels, we estimate the total amount of survival craft maintained by the affected population to be 31,729. Table 4 shows

the breakdown of the survival craft across the existing vessel population as follows: 2,612 inflatable buoyant apparatuses (IBAs), 23,748 liferafts, 2,835 lifeboats, and 2,534 rescue boats.

TABLE 4—VESSEL AND SURVIVAL CRAFT POPULATION

		Total number	IBAs	Inflatable liferafts	Lifeboats	Rescue boats	All survival craft
Subchapter	Type of vessel	of vessels (a)	Total (b)	Total (d)		Total (e)	
				Total (c)			Total (f)
C	Commercial Fishing Vessels.	6,022	248	6,267	141	52	6,708
C	Uninspected Passenger Vessels.	173	10	258	2	7	277
D	Tank	323	3	706	543	49	1,301
Н	Passenger	191	640	444	91	286	1,461
1	Cargo	1,037	3	3,247	1,200	618	5,068
I–A	Mobile Offshore Drilling Units.	57	0	263	623	37	923
Κ	Small Passenger	311	512	950	2	164	1,628
L	Offshore Supply Vessels	338	0	1,393	55	322	1,770
M	Towing Vessels	1,434	91	1,485	2	51	1,629
R	Nautical Schools	29	2	140	79	22	243
R	Sailing Schools	10	0	24	1	7	32
T	Small Passenger	4,231	1,025	7,506	5	830	9,366
U	Oceanographic Research	74	3	260	53	36	352
Other Ves- sels.		517	75	805	38	53	971
Total	14,747	2,612	23,748	2,835	2,534	31,729	

Table 5 presents vessels by the subchapter to which they are inspected in 46 CFR. "Other vessels" includes public and recreational vessels not subject to inspection. The owners and operators of the 14,747 identified vessels will experience cost savings from the lower estimated cost of replacing equipment. We used this existing vessel population data from MISLE and multiplied it by the average number of IBAs, liferafts, lifeboats, and rescue boats per vessel, which we also retrieved from MISLE, to obtain our estimated survival craft population. The estimated survival craft population is the number of survival craft that will need to replace non-durable Coast Guard-approved equipment over the next 10 years. The replacement

equipment will be less expensive, because the replacement equipment will not need Coast Guard approval. Those vessels with previously approved survival craft equipment will not be required to replace their survival craft equipment until the equipment expires or becomes unserviceable.

After establishing the existing number of current survival craft, we then estimated the growth in the number of survival craft each year in order to project our affected population for the next 10 years. To calculate the number of new survival craft each year, we multiplied the "Number of New Vessels per Year" by each "Average per Vessel" column to obtain our annual totals for each new survival craft type. We estimate that 25 new IBAs, 222 new

liferafts, 33 new lifeboats, and 31 new rescue boats will be outfitted with equipment subject to this rule each year.

We then sum the totals for each survival craft type across each affected subchapter to obtain our estimated population of new survival craft each year for this final rule. This annual growth in the survival craft population provides an estimate of the number of new survival craft that will enter the market each year. The vessel owners and operators of these craft will experience cost savings from buying some equipment, as discussed in this final rule, which will no longer need Coast Guard approval. Table 5 presents the estimated total number of new survival craft each year.

TABLE 5—AVERAGE SURVIVAL CRAFT PER VESSEL

		New	IBAs		Inflatable	liferafts	Lifeb	oats	Rescue boats	
Subchapter	Type of vessel	vessels per year	Average per vessel	Total	Average per vessel	Total	Average per vessel	Total	Average per vessel	Total
C	Commercial Fishing Ves- sels.	19	0.04	1	1.04	20	0.02	0	0.01	0
C	Uninspected Passenger Vessels.	1	0.06	0	1.49	1	0.01	0	0.04	0
D	Tank	5	0.01	0	2.19	11	1.68	8	0.15	1

⁷ We calculate the "Number of New Vessels per Year" column by taking the total number of new

TABLE 5—AVERAGE SURVIVAL CRAFT PER VESSEL—Continued

		New	IB	As	Inflatable	liferafts	Lifeb	oats	Rescue	boats
Subchapter	Type of vessel	vessels per year	Average per vessel	Total	Average per vessel	Total	Average per vessel	Total	Average per vessel	Total
Н	Passenger	2	3.35	7	2.32	5	0.48	1	1.50	3
1	Cargo	9	0	0	3.13	28	1.16	10	0.60	5
I–A	Mobile Off-	1	0	0	4.61	5	10.93	11	0.65	1
	shore Drill- ing Units.									
Κ	Small Pas- senger.	5	1.65	8	3.05	15	0.01	0	0.53	3
L	Offshore Sup- ply Vessels.	11	0	0	4.12	45	0.16	2	0.95	10
М	Towing Ves- sels.	22	0.06	1	1.04	23	0	0	0.04	1
R	Nautical Schools.	0	0.07	0	4.83	0	2.72	0	0.76	0
R	Sailing Schools.	0	0	0	2.40	0	0.10	0	0.70	0
Т	Small Pas- senger.	35	0.24	8	1.77	62	0	0	0.20	7
U	Oceano- graphic Re- search.	1	0.04	0	3.51	4	0.72	1	0.49	0
Other Vessels	Other Vessels	2	0.15	0	1.56	3	0.07	0	0.10	0
Total		113	6	25	37	222	18	33	7	31

Subchapters K and T Vessels

This rule also affects all U.S.-flagged vessel operators regulated under subchapters K and T, as these vessel operators are required to maintain a Coast Guard-approved first-aid kit onboard their vessels, in addition to any first-aid kits carried in the survival craft. The owners and operators of these small passenger vessels will no longer be required to maintain Coast Guard-approved first-aid kits aboard the vessels themselves. Using MISLE data,

we estimate there to be 5,982 existing small passenger vessels, with 40 new vessels being built on an annual basis. This number includes all small passenger vessels defined in subchapters K and T, found in §§ 121.710 and 184.710, respectively, regardless of what type of survival craft they have on board.

Equipment Type for Each Survival Craft

The type of equipment each survival craft is required to carry varies

depending on the intended use of the survival craft. Generally, survival craft intended for longer (international) voyages require more equipment than those intended to be used closer to shore. Lifeboats on inspected vessels generally must carry an equipment pack for an international voyage.⁸ Table 6 contains the equipment required by pack and type of survival craft.

⁸ With the exception of lifeboats on sailing school vessels, which must carry the equipment required in §§ 169.527 and 169.529.

Table 6:	Table 6: Required Survival Craft Equipment Subject to the Final Rule for Lifeboats, Liferafts, Rescue Boats, and IBAs											
	Types of Equipment Required											
	Lifeb	oats		Liferafts	_	Rescu	e Boats					
Equipment	International Voyage	Short International Voyage***	International Voyage (SOLAS A pack)	Voyage International (SOLAS A Voyage		International Voyage Short International Voyage***		IBAs				
Bilge pump	1	1						i				
Can Opener*	3	3	3					1				
Compass	1	1				1	1					
Fire extinguisher	1	1				1	1	i				
First-aid kit	1	1	1	1		1	1	1				
Fishing kit	1											
Hatchet	2	2										
Jackknife**	1	1										
Knife**			1	1	1	1	1	2				
Mirror, Signaling	1	1	1	1	1			1				
Sea anchor	1	1	2	2	1	1	1	1				
Water (liters per person)	3	1.5	3									

Sources:

International Voyage: 46 CFR 199.175

IBAs: 46 CFR 160.010-3

Coastal Service pack: 46 CFR 160.051-9

Notes:

^{* § 199.175(}b)(5) allows jackknives to take the place of a can opener.

^{**} This rule removes the separate requirements for knives and jackknives and, instead, requires that all survival craft be equipped with either knives or jackknives.

^{***} According to § 70.10-1, a short international voyage is an international voyage in the course of which a vessel is not more than 200 miles from a port or place in which the passengers and crew could be placed in safety. Neither the distance between the last port of call in the country in which the voyage begins and the final port of destination nor the return voyage may exceed 600 miles. The final port of destination is the last port of call in the scheduled voyage at which the vessel commences its return voyage to the country in which the voyage began.

Equipment Pack Types for Commercial Fishing Vessels

Commercial fishing vessels must be equipped with either a Coastal Service

pack, a SOLAS A pack, or a SOLAS B pack, depending on vessel size, distance traveled, whether the ocean route is designated as a cold-water route or

warm-water route, and the number of persons on board. Table 7 provides a brief description of the packs that can be carried by lifeboats and liferafts.⁹

TABLE 7—DESCRIPTION OF PACKS CARRIED BY LIFEBOATS AND LIFERAFTS

Type of pack	Contents
Coastal Service pack	A Coastal pack will contain a Sea Anchor (Automatically Deployed), Floating/Heavy Line (Length 100 feet), Rain Water Collector, Floatable Knife, Waterproof Equipment Bag, Raft Use Instructions, Individual Thermal Protective Aids (2 nos.), Floatable Paddles (1 pair), Manual Inflation/Bilge Pump, Repair Clamps (6 nos.), Adhesive and Patch Repair Kit.
SOLAS B pack	In addition to the items listed in the Coastal pack, a SOLAS B pack will contain: Waterproof Flashlight, a Spare Flashlight Bulb, Spare Flashlight "D" Cell Batteries (3 nos.), Sponges (2 nos.), Bailer, SOLAS Handheld Flares (3 nos.), SOLAS Rocket Parachute Flares (2 nos.) Buoyant Smoke Signal (1 no.), Seasick Bags (1 per person), Water Storage Bag, Thermal Protective Aid, Heliograph Mirror (for signaling), First-Aid Kit, Signaling Whistle, Anti-Seasickness Pills (6 Per Person), Spare Sea Anchor.
SOLAS A pack	In addition to the items listed in the Coastal pack and the items listed in SOLAS A pack will include: a Graduated Drinking Cup, Drinking Water (6 to 20 Person Capacity), Food Ration (10kj per Person), Can Opener, Fishing Kit, SOLAS Handheld Flares (Total 6 nos.) and a SOLAS Rocket Parachute Flare (Total 4 nos.).

Equipment Pack Types for Survival Craft

We used vessel route types from MISLE to estimate the percentage of vessels with a SOLAS A pack compared to a SOLAS B pack. We presume that all vessels with "Ocean" listed as a route type carry survival craft with SOLAS A packs. We estimate the remaining route types, not listed as "Ocean," will have SOLAS B packs. Using commercial fishing vessel data from MISLE and knowledge from subject matter experts from the Coast Guard's Lifesaving & Fire Safety Division (CG-ENG-4), who specialize in survival craft data, we

estimate that 50 percent of nonoceangoing fishing vessels will have Coastal Service packs and 50 percent of non-oceangoing fishing vessels will have SOLAS B packs.

We created a distribution of SOLAS A, SOLAS B, and Coastal Service packs by pulling all U.S.-flagged vessels by the inspection subchapter and then pulling these vessels by route type from the MISLE database. We excluded any vessels that did not have survival craft or had an unknown field for survival craft in the MISLE database. The route-type designation included "Ocean" for oceangoing vessels in MISLE, which we designated as SOLAS A vessels. 10 We

designated the remainder as SOLAS B vessels, except for commercial fishing vessels.¹¹ We then calculated the number of SOLAS A packs by dividing the population of our vessels (by subchapter) by the sum of vessels that had "Ocean" routes and dividing that sum by the sum of vessels in that given subchapter. To calculate the percentage of SOLAS B packs, we simply subtracted the number of SOLAS A packs from 100 percent. This data pull provided the total number of inflatable liferafts and lifeboats, respectively, and the percentage of each survival craft pack type by subchapter, which is presented in table 8.

TABLE 8—PERCENTAGE OF EQUIPMENT PACK TYPES FOR LIFEBOATS AND LIFERAFTS BY SUBCHAPTER

Type of vessel	Total number of vessels (a)	Number of oceangoing vessels (b)	Coastal service pack (c) (percent)	Short international/ SOLAS B (d) (percent)	International/ SOLAS A (e) (percent)
Commercial Fishing (Subchapter C)	6,022	3387	22	22	56
Uninspected Passenger (Subchapter C)	173	105		39	61
Tank (Subchapter D)	323	313		3	97
Passenger (Subchapter H)	191	67		65	35
Cargo and Miscellaneous (Subchapter I)	1037	974		6	94
Mobile Offshore Drilling Units (Subchapter I-A)	57	55		4	96
Small Passenger (Subchapter K)	311	6		98	2
Offshore Supply (Subchapter L)	338	335		1	99
Towing (Subchapter M)	1434	1123		22	78
Nautical Schools (Subchapter R)	29	28		3	97
Sailing Schools (Subchapter R)	10	2		80	20
Small Passenger (Subchapter T)	4231	872		79	21
Oceanographic Research (Subchapter U)	74	42		43	57
Other	517	300		42	58

Note: Totals may not sum due to rounding.

affected population that will carry Coastal Service packs instead of only having SOLAS B packs for short international shipping routes.

⁹Readers can find more information on inflatable liferafts for domestic service at https://ecfr.io/Title-46/sp46.6.160.160_1051.

¹⁰The "Ocean" designation in MISLE specifically refers to vessels with SOLAS certificates that

designate them as SOLAS A vessels. The MISLE data being pulled is from 2008–2020.

¹¹We broke out the Coastal routes and short international routes by vessel, because Commercial Fishing Vessels are the only type of vessels in our

We then estimated the number of liferafts and lifeboats by equipment pack type for existing and new vessels by looking at the total number of packs carried by lifeboats and liferafts. Table 9 presents the number of SOLAS A, SOLAS B, and Coastal Service packs by liferaft and lifeboat for each subchapter of vessels.

We calculated the total number of inflatable liferafts with Coastal Service Packs (column (a) in table 9) by multiplying the percentage of Coastal Service Packs in liferafts and lifeboats (column (c) in table 8) by the total number of inflatable liferafts by subchapter (column (c) in table 4). We

calculated column (b) in table 9, "Short International/SOLAS B packs for inflatable liferafts," by multiplying column (d) in table 8, which is the percentage of Short International/ SOLAS B packs by vessel subchapter, by column (c) in table 4, which is the total number of inflatable liferafts by subchapter. We calculated column (c) in table 9, "International/SOLAS A packs for liferafts," by multiplying column (e) in table 8, which is the percentage of International/SOLAS A packs by vessel subchapter, by column (c) in table 4, which is the total number of inflatable liferafts by subchapter. We calculated column (e) in table 9, "Short

International/SOLAS B packs for lifeboats," by taking the sum of multiplying columns (c) and (d), the percentages of Coastal packs and Short International/SOLAS B packs in table 8 by column (d) in table 4, which is the total number of lifeboats by subchapter. Finally, we calculated column (f) in table 9, "International/SOLAS A packs for lifeboats" by multiplying column (e) from table 8, which is the percentage of International Packs/SOLAS A, by column (d) in table 4, which is the total number of lifeboats by subchapter.

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		Inflatable L	iferafts			Lifeboa	ts
Type of Vessel	Coastal Service pack (a)	Short International / SOLAS B (b)	International / SOLAS A (c)	Total (a) + (b) + (c) = (d)	Short International / SOLAS B (e)	International/ SOLAS A (f)	Total (e) + (f) = (g)
Commercial Fishing Vessels	(a)	(6)	(6)	(u)	(6)	(1)	10tar(c) + (1) - (g
(Subchapter C)	1,371	1,371	3,525	6,267	62	79	141
Uninspected Passenger Vessels (Subchapter C)	-	101	157	258	1	1	2
Tank (Subchapter D)	-	22	684	706	17	526	543
Passenger (Subchapter H)	-	288	156	444	59	32	91
Cargo and Miscellaneous (Subchapter I)	-	197	3,050	3,247	73	1,127	1,200
Mobile Offshore Drilling Units (Subchapter I-A)	-	9	254	263	22	601	623
Small Passenger (Subchapter K)	-	932	18	950	2	0	2
Offshore Supply Vessels (Subchapter L)	-	12	1,381	1,393	0	55	55
Towing Vessels (Subchapter M)	-	322	1,163	1,485	0	2	2
Nautical Schools (Subchapter R)	-	5	135	140	3	76	79
Sailing Schools (Subchapter R)	-	19	5	24	1	0	1
Small Passenger (Subchapter T)	-	5,959	1,547	7,506	4	1	5
Oceanographic Research (Subchapter U)	-	112	148	260	23	30	53
Other Vessels	-	338	467	805	16	22	38
Total	1,371	9,687	12,690	23,748	283	2,552	2,835

distribution in table 8 to obtain the number of new packs needed for the new liferafts and lifeboats on vessels each year.

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TABLE 10—LIFEBOATS AND LIFERAFTS BY EQUIPMENT PACK TYPE NEEDED ON AN ANNUAL BASIS BROKEN OUT BY SUBCHAPTER

		Inflatable	liferafts			Lifeboats	
Type of vessel	Coastal service pack	Short international/ SOLAS B	International/ SOLAS A	Total	Short international/ SOLAS B	International/ SOLAS A	Total
Commercial Fishing (Subchapter C)	4	5	11	20	0	0	0
Uninspected Passenger (Subchapter C)		0	1	1	0	0	0
Tank (Subchapter D)		0	11	11	0	8	8
Passenger (Subchapter H)		3	2	5	1	0	1
Cargo and Miscellaneous (Subchapter I)		2	26	28	1	9	10
Mobile Offshore Drilling Units (Subchapter							
I–A)		0	5	5	0	11	11
Small Passenger (Subchapter K)		15	0	15	0	0	0
Offshore Supply (Subchapter L)		0	45	45	0	2	2
Towing (Subchapter M)		5	18	23	0	0	0
Nautical Schools (Subchapter R)		0	0	0	0	0	0
Sailing Schools (Subchapter R)		0	0	0	0	0	0
Small Passenger (Subchapter T)		49	13	62	0	0	0
Oceanographic Research (Subchapter U)		2	2	4	0	1	1
Other Vessels		1	2	3	0	0	0
Total	4	82	136	222	2	31	33

Note: Values may not sum due to rounding.

Benefits

In addition to the nonquantified benefits discussed in table 2, this rule will generate a cost savings as follow:

Cost Savings

This rule will generate a cost savings to: (1) vessel owners and operators from having the option to purchase less expensive survival craft equipment; (2) equipment manufacturers from reducing reporting, recordkeeping, and production requirements of survival craft equipment; and (3) the Federal Government from reducing recordkeeping requirements. The details and calculations of the cost savings are discussed later in this final rule.

Wages

This rule will reduce the burden of review that is required by both industry and the Federal Government. This review includes preparing COA applications, renewals, and product instructions by certain manufacturers. We presume clerical employees will be responsible for all the manufacturer's recordkeeping activities, and production employees will be responsible for marking equipment and packing instructions. Federal Government employees who possess the technical knowledge to review submissions to ensure safety standards will be senior engineers at the GS-14 grade. These employees will be responsible for the review of all the submitted information.

We calculate the costs for each activity by estimating the labor hours

required in each labor category and then multiplying those burdens by the wage rate for each labor category. For this analysis, we calculated private sector wages using 2020 wage data from the U.S. Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) for the miscellaneous manufacturing sector (North American Industry Classification System (NAICS) 339000).12 We added a load factor to the industry wages using December 2020 wage and total compensation data from the BLS Employer Costs for Employee Compensation (ECEC) survey, which accounts for employee benefits. This load factor represents the total benefits as a percentage of total salary.¹³ Table 11 summarizes the loaded wage rates for industry used in this RA.

TABLE 11—DERIVATION OF 2020 LOADED INDUSTRY WAGE RATES

[Rounded to the nearest dollar]

Personnel		2020 hourly wage	Load factor	Loaded hourly wage
category	Data source(s)	wage		waye
category		(a)	(b)	$(c) = (a) \times (b)$
Technical	Wage Rate: Mean hourly wage for Industrial Engineers, including Health and Safety: Occupation code (17–2110) under the miscellaneous manufacturing sector (NAICS 339000) from the BLS OES. Link: https://www.bls.gov/oes/2020/may/naics3 339000.htm#17-0000.	\$44.10	1.51	\$67

¹² https://www.bls.gov/oes/2020/may/naics3_339000.htm.

compensation by wages and salaries. For this analysis, we used BLS' Employer Cost for Employee Compensation/Manufacturing Occupations, Private Industry report (Series IDs, CMU2013000000000D and CMU2023000000000D for all workers using the multi-screen data search). Using 2020 Quarter 4 Manufacturing data, we divided the total compensation amount of \$40.02 by the wage and

salary amount of \$26.56 to get the load factor of 1.51 (\$40.02 divided by \$26.56). This data is found in table 4 of the Employer Costs for Employee Compensation December 2020 News Release available at Employer Costs for Employee Compensation Archived News Releases: U.S. Bureau of Labor Statistics (bls.gov).

¹³ A loaded labor rate is what a company pays per hour to employ a person beyond the hourly wage. Instead, the loaded labor rate includes the cost of benefits (health insurance, vacation, etc.). We calculate the load factor for wages by dividing total

TABLE 11—DERIVATION OF 2020 LOADED INDUSTRY WAGE RATES—Continue	ed
[Rounded to the pearest dollar]	

Personnel	Data source(s)	2020 hourly wage	Load factor	Loaded hourly wage
category	Duid States(c)	(a)	(b)	$(c) = (a) \times (b)$
Clerical	Loading Factor: Calculated from December 2020 BLS ECEC non-seasonally adjusted data for wage and salaries (CMU2013000000000D) and total compensation (CMU202300000000D) for private industry workers in the miscellaneous manufacturing sector. Wage Rate: Mean hourly wage for Information and Record Clerks: Occupation code (43–4000) under the miscellaneous manufacturing sector (NAICS 339000) from the BLS OES. Link: https://www.bls.gov/oes/2020/may/naics3_339000.htm#43-4000. Loading Factor: Calculated from December 2020 BLS ECEC non-seasonally adjusted data for wage and salaries (CMU201300000000D) and total compensation (CMU202300000000D) for private industry	\$19.87	1.51	\$30
Production	workers in the manufacturing sector. Wage Rate: Mean hourly wage for Assemblers: Occupation code (51–2000) in the miscellaneous manufacturing sector (NAICS 339000) from the BLS OES. Link: https://www.bls.gov/oes/2020/may/naics3_339000.htm#51-2000. Loading Factor: Calculated from December 2020 BLS ECEC non-seasonally adjusted data for wage and salaries (CMU201300000000D) and total compensation (CMU202300000000D) for private industry workers in the manufacturing sector.	\$17.22	1.51	\$26

For Federal Government employees, The Office of Personnel Management (OPM) lists the hourly pay for Federal employees according to the Washington, DC area General Schedule (GS) pay tables. 14 OPM records the hourly pay of GS-14, step 5 (the midpoint of the pay band) as \$65.88. We calculate the share of total compensation of Federal employees to account for a government employee's non-wage benefits. The Congressional Budget Office (2017) reports total compensation to Federal employees as \$64.80 per hour and wages as \$38.30.15 We determine the load factor to be approximately 1.69.16 We multiplied \$65.88 by 1.69 to obtain a loaded hourly wage rate of approximately \$111.34 for a GS-14 senior engineer.

Cost Savings to Equipment Manufacturers

We estimate that manufacturers of Coast Guard-approved equipment will have a cost savings associated with no longer having to complete applications to obtain and maintain Coast Guard approval. In addition, this rule will remove recordkeeping and reporting requirements, and reduce testing requirements for some pieces of survival equipment.

Number of Survival Craft Products

This rule modifies the approval requirements for nine categories of survival craft equipment. In total, there are 28 approvals for these 9 categories of survival craft equipment. These are the specific items that vessel owners and operators purchase to comply with the vessel carriage regulations found in 46 CFR chapter I, subchapters C, T, K, and W.¹⁷ These items are required to be stowed on board survival craft.

To comply with the lifesaving equipment regulations in 46 CFR chapter I, subchapter Q, manufacturers submit an application to the Coast Guard for review and approval. Once approved, the manufacturer of each piece of equipment must mark it (or stamp it) with its approval number (see table 12).

There are two types of survival craft equipment: (1) items that are durable and need not be replaced or serviced

frequently, such as bilge pumps, compasses, fishing kits, 18 jackknives, signaling mirrors, hatchets, and sea anchors; and (2) items that are not durable, expire, and must be replaced, such as first-aid kits and emergency drinking water. We used the annual total number of pieces of survival craft equipment needed to stock new survival craft in order to forecast the number of new pieces of equipment manufactured and stamped on an annual basis. We estimate that, in the long term, the supply of new survival equipment will equal the demand of new survival craft equipment.

The Coast Guard does not have substantive data on how long these durable goods last, and we estimate that these goods will last as long as the survival craft themselves.

We discuss the renewal rate of nondurable goods, first-aid kits, and water later in this analysis.¹⁹ Table 12 lists the estimated number of pieces of survival craft equipment manufactured on an annual basis.

¹⁴ https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/20Tables/html/DCB_h.aspx.

¹⁵ Congressional Budget Office (2017), "Comparing the Compensation of Federal and Private-Sector Employees, 2011 to 2015," https:// www.cbo.gov/system/files/115th-congress-2017-2018/reports/52637-federalprivatepay.pdf.

¹⁶ \$64.80 divided by 38.30.

¹⁷ Refer to the appendix titled "Appendix C: Carriage Requirements for all the Survival Craft Equipment" in the docket folder for more information on carriage requirements for all vessels affected by this final rule.

¹⁸There is currently one Coast Guard-approved fishing kit on CGMIX. The only non-durable aspect of the fishing kit is the bait, which is made of a synthetic resin known as plastisol. If stored properly, plastisol has an indefinite shelf life.

¹⁹Refer to the sections titled *First-Aid Kits, First-Aid Kits for Liferafts and IBA*, and *Emergency Water* further in the regulatory analysis.

TABLE 12—ESTIMATED NUMBER OF PIECES OF EQUIPMENT MANUFACTURED ANNUALLY

Equipment	Approval series	Annual number of pieces of equipment
Compass	160.014	87
First-aid kit for Lifeboats	160.041	188
First-aid kit for Liferafts	160.054	285
Fishing kit	160.061	38
Hatchet	160.013	92
Jackknife	160.043	46
Mirror, Signaling	160.020	338
Total		1,074

Equipment Approval and Markings

In the current regulations, manufacturers seeking Coast Guard approval must submit a COA application with information such as technical plans, drawings, specifications, instructional materials, and test reports. In addition to the initial application, manufacturers of

Coast Guard-approved equipment must also submit application renewals every 5 years to maintain their approval status. Table 3 presents the estimated number of new COA applications for each equipment type, as the annual average number of new products each year.

Table 13 presents the estimated number of application renewals for each

equipment type. Since the Coast Guard estimates that 1 of every 5 applications will be renewed on an annual basis, the number of renewal applications is equal to 20 percent of the total number of products. Once a product has been approved, the manufacturer must stamp each individual piece of survival craft equipment with the Coast Guard approval number and other information.

TABLE 13—TOTAL NUMBER OF NEW RENEWALS

Equipment	Approval series	Total products	Annual percentage of COAs for renewals	Total renewal applications annually
		(a)	(b)	$(c) = (a) \times (b)$
Bilge pump	160.044	3	20	0.6
Compass	160.014	3	20	0.6
Compass First-aid kit for Lifeboats*	160.041	5	20	1
First-aid kit for Liferafts	160.054	5	20	1
Fishing kit	160.061	1	20	0.2
Hatchet	160.013	1	20	0.2
Jackknife	160.043	1	20	0.2
Mirror, Signaling	160.020	2	20	0.4
Sea anchor	160.019	1	20	0.2
Water**	160.026	6	20	1.2
Total		28	20	6

Note: Values may not sum due to rounding.

We estimate that it will take the technical staff 2 hours to prepare a new application, and the clerical staff will spend 0.17 hours (10 minutes) ²⁰ per application on recordkeeping, for a total cost of \$139 per new application [(2)]

 $^{\rm 20}\,\rm Based$ on information from the subchapter Q ICR.

technical hours \times \$67) + (0.17 clerical hours \times \$30) = \$139]. For renewal applications, we estimate a burden of 0.5 technical hours and 0.17 clerical hours, for a total cost of \$39 [(0.5 technical hours \times \$67) + (0.17 clerical hours \times \$30) = \$39]. Under this rule, the Coast Guard no longer requires approval applications for any new survival craft

equipment. As shown in table 14, we estimate this will result in a cost saving to industry of approximately \$117 per year for new applications, and approximately \$219 per year for renewal applications. This results in a total annual cost savings of about \$336.

^{*}This includes the first-aid kits described in the subchapters K and T section of this preamble, which are covered under the same approval subpart in the CFR.

^{**}For emergency drinking water, this only includes implementation in the first 5 years of the analysis period. We present the number of affected products in Years 6 through 10 of the analysis period later in this RA.

TABLE 14—ANNUAL COST SAVINGS OF INDUSTRY FOR NO LONGER HAVING TO SUBMIT NEW AND RENEWAL CERTIFICATE OF APPROVAL APPLICATIONS

		New appli	cations	Renewal ap		
Equipment	Approval series	Total number of applications *	Total cost savings	Total number of applications **	Total cost savings	Total cost savings
		(a)	(b) = (a) × [-\$139]	(c)	(d) = (c) × [-\$39]	(e) = (b) + (d)
Bilge pump	160.044	0.09	-\$13	0.60	-\$23	-\$36
Compass	160.014	0.09	-13	0.60	-23	- 36
First-aid kit for Lifeboats	160.041	0.15	-21	1.00	- 39	-60
First-aid kit for Liferafts	160.054	0.15	-21	1	-39	-60
Fishing kit	160.061	0.03	-4	0.20	-8	- 12
Hatchet	160.013	0.03	-4	0.20	-8	- 12
Jackknife	160.043	0.03	-4	0.20	-8	- 12
Mirror, Signaling	160.020	0.06	-8	0.4	- 16	-24
Sea anchor	160.019	0.03	-4	0.20	-8	- 12
Water	160.026	0.18	-25	1.20	-47	-72
Total			-117		-219	- 336

The Coast Guard is removing requirements that equipment must be marked with a Coast Guard approval number. With the exception of compasses and hatchets, equipment needs to be marked only to indicate that it meets standards set in ISO 18813. Compasses will no longer need to be marked with their Coast Guard approval number, but will still need to be marked to indicate they meet ISO 25862, as is currently required by the Coast Guard approval guidelines for magnetic compasses in lifeboats and rescue boats. Hatchets will not need to be marked at all, as they do not have to meet any consensus standard and because this rule removes the marking required by § 160.013-5.

The Coast Guard assumes the burden to mark the equipment is the same whether it is marked with a Coast Guard approval number or whether it is marked indicating that it meets the ISO standard; therefore, this change will only result in a cost savings to the manufacturers of hatchets. The Coast Guard estimates that it takes industry 0.06 hours of production labor time 21 to mark each individual piece of equipment at a cost of \$1.56 (0.06 hours \times \$26 = \$1.56) per piece of equipment. We estimate that 92 hatchets will no longer need to be marked each year (see table 12), for a total cost savings of approximately \$144 (\$1.56 \times 92).

Instructions

The Coast Guard currently requires that equipment manufacturers provide instruction material with certain types of equipment to ensure that crew members have access to information on the proper use of the equipment. We currently require instructions for five of the nine types of equipment subject to this rulemaking: compasses, first-aid kits, mirrors, fishing kits, and jackknives. ISO 18813 requires instructions for three types of equipment: first-aid kits, mirrors, and fishing kits. ISO 18813 does not state that instructions need to be provided for

compasses and jackknives; therefore, the manufacturers of compasses and jackknives will no longer have to develop and maintain instructions for their products under this rule.

Based on information in the current subchapter Q ICR (OMB Control Number 1625–0035), we estimate that it takes about 8 hours of time to prepare a set of instructional materials for new equipment, for a cost of about \$536 (8 hours \times \$67/hour).

Table 15 presents the total annual industry cost savings, \$64, for no longer having to develop new instructions for some types of new survival craft equipment. The total cost in columns (b) and (d), \$536, is the loaded wage of a safety engineer and inspector, \$67, multiplied by the estimated burden of work, 8 hours, for preparing a set of new instructions. This table presents the baseline scenario burden, the proposed post-regulatory scenario burden, and the difference between the two as cost savings.

TABLE 15—ANNUAL COST SAVINGS OF MODIFYING NEW INSTRUCTION REQUIREMENTS FOR APPLICABLE EQUIPMENT

	A	Baselin	e scenario	Post-regula	Total cost		
Equipment	Approval series	Total new instructions	Total cost	Total new instructions	Total cost	savings	
		(a)	(b) = (a) \times \$536	(c)	$(d) = (c) \times 536	(e) = (d) - (b)	
Compass	160.014	0.09	\$48	0	\$0	-\$48	
First-aid kit for Lifeboats	160.041	0.15	80	0.15	80	0	
First-aid kit for Liferafts	160.054	0.15	80	0.15	80	0	
Fishing kit	160.061	0.03	16	0.03	16	0	
Jackknife	160.043	0.03	16	0	0	-16	
Mirror, Signaling	160.020	0.06	32	0.06	32	0	
Total		0.51	272	0.39	208	- 64	

Note: Totals may not sum due to rounding.

^{*}Refer to column (c) in table 3.
**Refer to column (c) in table 13.

²¹ This is based on information from the subchapter Q ICR.

 $^{^{\}rm 22}\,{\rm This}$ value is incorporated in column (a) of table 19.

Laboratory Testing and Recordkeeping

As current regulations stand, the Coast Guard requires product testing and recordkeeping for some lifesaving equipment to ensure the equipment meets minimum performance

requirements. Table 16 presents a comparison of the current Coast Guard testing requirements and the testing requirements stated in ISO 18813 and ISO 25862 (for compasses). This table also contains a qualitative description of the change in costs associated with

modifying the current testing requirements. We were unable to obtain any cost data from the Coast Guardapproved labs that conduct the testing of this equipment, and we received no comments to the NPRM on this.23

TABLE 16—PREVIOUS AND NEW PRODUCT TESTING REQUIREMENTS

Product	Previous testing requirements	New testing requirements	Cost impact
Compasses	All testing requirements from section 4 of ISO 613 a. Dry Heat a Low Temperature a Vibration a Solar Radiation a Corrosion a	All testing requirements for class B Compasses as stated in ISO 25862. Dry Heat Damp Heat Low Temperature Vibration Solar Radiation Corrosion	No cost change, as the requirements of ISO 613 and ISO 25862 are not substantively different.
Bilge Pump	Capacity Testing b Head Pressure Testing b. Operating Lever Testing b.	Capacity Testing Head Pressure Testing Operating Lever Testing	None. Testing requirements are the same.
Jackknife	Hardness Test c Bending and Drop Tests c Cutting Tests c	Cutting Tests	Unquantified cost savings. The Coast Guard is unable to assess the change in burden; there is no substantive data.
First-Aid for Lifeboats	Accelerated weathering d Salt spray d Temperature change d Container watertightness d. Carton watertightness d	None	Unquantified cost savings. There is no change in testing requirements; therefore, there is no change in burden.
First-Aid for Liferafts	Accelerated weathering e Salt Spray e	• None	Unquantified cost savings. There is no change in testing requirements; therefore, there is no change in burden.
Mirrors	Reflection Test f Flatness Tests f Dropping Test f Salt Spray f Watertightness	Reflection Test Flatness Test Dropping Test Oil-Resistance Test Lanyard Strength Test	Unknown change in cost. The Coast Guard is unable to assess the change in burden as there is no substantive data.
Emergency Water	Chemical and biological analysis. Temperature Storage Leakage Water Immersion Testing Durability Corrosion Drop	Water quality must be verified by the local municipality or independent lab. Low and High Temperature Storage. Leakage Water Immersion Testing Durability Corrosion Drop	None. Testing requirements are the same, as under the ISO standard the water must satisfy international chemical and microbiological requirements. Concerning the water quality testing, the Coast Guard was unable to obtain any cost data from the laboratories.

Sources:

a "United States Coast Guard Approval Guideline for Magnetic Compasses in Lifeboats/Rescue Boats," USCG Approval Series 160.014, December 2005.

Based on the information from the current subchapter Q ICR, we estimate that recordkeeping takes 2 hours of clerical time per year and costs \$60 (2 hours \times \$30 clerical staff loaded hourly wage rate). The Coast Guard is removing

the requirements for testing records for seven types of equipment listed in this final rule, as these manufacturers no longer need these records to document that their products meet the requirements of the ISO 18813. Table 17

presents the total cost savings of about \$1,500 to industry from removing requirements to keep records of laboratory testing. The \$60 figure used in calculating total cost in columns (b) and (d) represents the loaded hourly

b § 160.044–4 c § 160.043–5 d § 160.041–5

e § 160.054–5

Documentation provided by subject matter experts in CG-ENG-4.

²³ We asked four Coast Guard-approved laboratories for cost estimates for the testing

requirements, but the labs were unable to provide any cost information.

wage of a record clerk (\$30) multiplied by the estimated burden of work for fulfilling recordkeeping requirements (2 hours). This table presents the baseline scenario burden and the post-regulatory scenario burden and then presents the difference of the two burdens as cost savings.

TABLE 17—ANNUAL COST SAVINGS TO MANUFACTURERS FOR TESTING RECORDKEEPING REQUIREMENTS

	Approval	Baselin	e scenario	Post-regula	Total cost	
Equipment	Approval - subpart	Total products	Total cost	Total products	Total cost	savings
		(a)	(b) = (a) \times \$60	(c)	(d) = (c) \times \$60	(e) = (d) - (b)
Bilge pump	160.044	3	\$180	0	\$0	-\$180
Compass	160.014	3	180	0	0	- 180
First-aid kit for Lifeboats	160.041	5	300	0	0	-300
First-aid kit for Liferafts	160.054	5	300	0	0	-300
Jackknife	160.043	1	60	0	0	-60
Mirror, Signaling	160.020	2	120	0	0	- 120
Water	160.026	6	360	0	0	-360
Total		25	1,500	0	0	- 1,500

Note: Totals may not sum due to rounding.

Laboratory Inspections

The Coast Guard currently requires inspectors to examine the manufacturing process in order to ensure that quality control is maintained. This rule removes these requirements; however, the Coast Guard is unable to determine if this removal will generate any cost savings to industry. Hence, the Coast Guard is not quantifying it as a cost savings. Manufacturers are likely to still have their production line inspected to ensure quality as part of best industry

practices. Moreover, manufacturers may continue third-party testing to maintain certifications, such as the ISO 9001 standard, or to meet other regulatory obligations. At the time of this final rule, the Coast Guard does not have enough information to quantify any potential changes in cost resulting from the changes in inspection requirements.

Additionally, the Coast Guard requires inspecting entities to issue annual reports to enable a comparison between the production line and the prototype tested by the Coast Guard.²⁴ We were able to estimate a cost savings

that resulted from the removal of this reporting requirement using information from the subchapter Q ICR, which estimated that this recordkeeping takes 24 hours of clerical time per year on average and costs \$720 (24 hours × \$30 clerical wage rate). The Coast Guard is removing this reporting requirement for all types of survival craft equipment. As shown in table 18, we estimate a total annual cost savings of approximately \$17,280. This table presents the baseline scenario burden, the post-regulatory scenario burden, and the difference between the two as cost savings.

TABLE 18—ANNUAL COST SAVINGS FOR LABORATORY INSPECTION RECORDS

	Approval	Baselin	e scenario	Post-regula	Total change	
Equipment	series	Total products	Total cost	Total products	Total cost	in cost
		(a)	(b) = (a) × \$720	(c)	(d) = (c) \times \$720	(e) = (d) - (b)
Bilge pump	160.044	3	\$2,160	0	\$0	-\$2,160
Compass	160.014	3	2,160	0	0	-2,160
First-aid kit for Lifeboats	160.041	5	3,600	0	0	-3,600
First-aid kit for Liferafts	160.054	5	3,600	0	0	-3,600
Mirror, Signaling	160.020	2	1,440	0	0	- 1,440
Water	160.026	6	4,320	0	0	-4,320
Total		24	17,280	0	0	- 17,280

Note: Totals may not sum due to rounding.

Total Cost Savings to Manufacturers

Table 19 presents the annual total cost savings to equipment manufacturers.

We estimate that manufacturers of Coast Guard-approved bilge pumps, lifeboats, compasses, first-aid kits, fishing kits, hatchets, jackknives, signaling mirrors, sea anchors, and emergency water will save approximately \$19,324 per year.

TABLE 19—TOTAL ANNUAL COST SAVINGS TO EQUIPMENT MANUFACTURERS

Equipment	Approval series	Application and marking requirements	Instruction requirements	Product testing	Laboratory inspections	Total cost savings
		(a)	(b)	(c)	(d)	(e) = (a) + (b) + (c) + (d)
Bilge pump Compass	160.044 160.014	-\$36 -36	\$0 -48	-\$180 -180	-\$2,160 -2,160	-\$2,376 -2,424

²⁴ While the Coast Guard currently requires testing for jackknives, it does not require laboratory

Equipment	Approval series	Application and marking requirements	Instruction requirements	Product testing	Laboratory inspections	Total cost savings
		(a)	(b)	(c)	(d)	(e) = (a) + (b) + (c) + (d)
First-aid kit for Lifeboats First-aid kit for Liferafts Fishing kit Hatchet Jackknife Mirror, Signaling Sea anchor Water	160.041 160.054 160.061 160.013 160.043 160.020 160.019 160.026	-60 -60 -12 -156 -12 -24 -12 -72	-0 -0 -0 0 -16 -0 0	-300 -300 0 0 -60 -120 0 -360	-3,600 -3,600 0 0 -1,440 0 -4,320	- 3,960 - 3,960 - 12 - 156 - 88 - 1,584 - 12 - 4,752
Total		-480	-64	- 1,500	- 17,280	- 19,324

TABLE 19—TOTAL ANNUAL COST SAVINGS TO EQUIPMENT MANUFACTURERS—Continued

Cost Savings to Vessel Owners or Operators

After gathering price data from a variety of sources, we estimate that removing approval requirements will allow owners and operators of vessels to purchase less expensive equipment.25 While there are several companies selling Coast Guard-approved equipment, online information generally does not specify whether the equipment meets ISO 18813 or similar standards. As a result, we had difficulty finding price data for survival craft equipment products clearly stating that they met ISO 18813 standards. However, we were able to identify prices for two products-emergency provisions and emergency water—that the manufacturer or advertiser explicitly stated met the requirements of the ISO 18813 standard.

We then applied percentage price difference between emergency water products and emergency provisions that had both Coast Guard approval and met the requirements of ISO 18813, and those emergency provisions and water products that met only the requirements of ISO 18813.²⁶ We estimate that products without Coast Guard approval affected by this rule were approximately 28 percent less expensive than products with Coast Guard approval.²⁷

We applied this 28-percent price decrease to all the products affected by this rule, with the exception of first-aid kits, because the kit content requirements differ between the ISO standard and current Coast Guard standards, and we estimate the change in price for first-aid kits by the difference in replacement costs for firstaid kits. These differences are explained in further detail in the section, First-Aid Kits, in this RA. For this analysis, we quantified the cost savings to new vessels from being able to purchase less expensive equipment, and the cost savings to existing vessels of replacing expired items with less costly items. For durable items, without data to estimate how frequently these items are replaced, we are not able to estimate the cost savings to the owners and operators of existing vessels for purchasing replacement equipment that we estimate will be 28 percent cheaper. However, since emergency water and first-aid kits expire, we estimate the cost savings for purchasing replacement equipment for the owners and operators of both new and existing vessels based on how frequently this non-durable equipment must be replaced. This information is presented later in this RA.

Durable Equipment: Bilge Pumps, Compasses, Fishing Kits, Hatchets, Jackknives, Mirrors, and Sea Anchors

We estimate that only new vessels will purchase bilge pumps, compasses, fishing kits, hatchets, jackknives, mirrors, and sea anchors for their survival craft. Based on population estimates (presented in table 5), 25 new

We were not able to derive this figure for all of the products due to lack of industry data. However, given the similarity of the equipment type, we assume the price differences would be similar for all products.

IBAs, 222 new liferafts, 33 new lifeboats, and 31 new rescue boats will be subject to this rule each year. Table 6 lists the survival equipment that lifeboats, liferafts, rescues boats, and IBAs are required to carry. We multiply the populations in table 5 by the carriage requirements in table 6 to yield the total number of items purchased for new survival craft in table 20. The Coast Guard requires new lifeboats to be equipped with bilge pumps, and there were 33 new lifeboats recorded in table 5, meaning there will be 33 purchases of new bilge pumps per year.28 Only the new lifeboats with equipment packs for international voyages will require fishing kits (see table 6), and all new lifeboats and rescue boats will be equipped with compasses, for a total of 64 purchases of compasses each year. All 280 new IBAs, liferafts, and lifeboats are required to be equipped with mirrors. Finally, 218 liferafts with a SOLAS A or SOLAS B pack will be equipped with 2 sea anchors each. This rule will require that 93 IBAs, lifeboats, rescue boats, and liferafts with coastal service packs each have 1 sea anchor.

Table 20 presents the annual cost savings from new vessels removing Coast Guard approval for bilge pumps, compasses, fishing kits, hatchets, jackknives, mirrors, and sea anchors. In total, we estimate an annual cost savings of approximately \$78,324 for U.S.-flagged vessels by removing the type approvals for these 7 types of survival craft equipment.

²⁵We looked at online retailers of survival craft equipment to assess price data. A search of online retailers determined that equipment that was not type-approved was less expensive than similar equipment that was type-approved.

²⁶ Although emergency provisions are not subject to changes in this final rule, we still examined them for the purposes of price comparison, as doing so provided a depth of data allowing us to determine a more robust ratio.

²⁷ We calculated this figure by finding the price differential for those products that were Coast Guard type-approved and those products that were not Coast Guard-approved but met ISO standards.

²⁸ The Coast Guard requires all non-self-bailing lifeboats and rescue boats to have bilge pumps. Based on discussions with subject matter experts in CG—ENG—4, the Coast Guard estimates that all new lifeboats will be non-self-bailing and will therefore require bilge pumps, and all new rescue boats that are not also lifeboats will be self-bailing and therefore will not require bilge pumps.

Table 20—Annual Cost Savings to New Vessels From Removing Coast Guard Approval for Bilge Pumps, Compasses, Fishing Kits, Hatchets, Jackknives, Mirrors, and Sea Anchors

Equipment	Average price of coast guard- approved equipment	Estimated equipment price without coast guard approval requirements	Difference	Number of survival craft	Average number of items per survival craft	Total cost savings
	(a)	(b) = (a) \times 0.72	(c) = (b) - (a)	(d)	(e)	$ (f) = (c) \times (d) \times (e) $
Bilge pump	\$276	\$199	-\$77	33	1	- \$2,541
Compass	1,250	900	-350	64	1	-22,400
Fishing kit	41	30	-11	31	1	-341
Hatchet	28	20	-8	33	2	-528
Jackknife	34	24	-10	33	1	-330
Mirror, Signaling	19	14	-5	280	1	-1,400
Sea anchor (Liferafts with SOLAS A and SOLAS B						
packs)	343	247	-96	218	2	-41,856
Sea anchor (Other Survival Craft)	343	247	-96	93	1	-8,928
Total						-78,324

Note: Totals may not sum due to rounding. All product prices are rounded to the nearest whole dollar.

Jackknives as a Replacement for Can Openers

As specified in § 199.175(b)(5), the Coast Guard allows jackknives to meet the requirements of a can opener, thereby permitting jackknives to fulfill two requirements. Table 1 in § 199.175 states that only lifeboats and rigid liferafts with SOLAS A packs require can openers, and only lifeboats may carry jackknives. This means that rigid liferafts with SOLAS A packs are currently carrying both knives and can openers. This rule will allow these vessels to replace their knives with jackknives, resulting in a cost savings to vessel owners from being able to purchase only a jackknife instead of both a knife and a can opener. We estimate that there are a total of 136 new liferafts each year that carry SOLAS A packs and, further, assume that these vessel owners and operators will choose to replace a knife with a jackknife, thus forgoing the need to purchase a can opener.29 We estimate the price of a can opener meeting the requirements of ISO 18813 to be \$6.30 Therefore, we estimate that vessel owners and operators will save \$816 (136 SOLAS A liferafts \times \$6 per can opener) for no longer needing

can openers, because of meeting the jackknife requirements.

Emergency Water

The Coast Guard requires survival craft with SOLAS A packs be stocked with 3 liters of water per person, and that lifeboats with SOLAS B packs be stocked with 1.5 liters of water per person. We estimate the average cost of Coast Guard-approved water to be \$4 per liter,³¹ while the cost of 1 liter of emergency water that meets the ISO 18813 standard to be \$3.32 The price difference between the Coast Guardapproved water and water approved under ISO 18813 is \$1 per liter.33 This is the estimated additional cost of Coast Guard approval, which is counted as cost savings. Emergency water expires and will need to be replaced every 5 years; therefore, the Coast Guard estimates that 20 percent of existing survival craft and 100 percent of new survival craft will need to purchase emergency water annually.

We estimate that industry will save a total of \$183,255 on an annual basis $(3,215 \text{ survival craft} \times 19 \text{ people per survival craft} \times 3 \text{ liters of water} \times $1 \text{ cost savings})$ for survival craft with SOLAS

A packs during Years 1 through 5 of implementation.³⁴ To calculate this cost savings, we took the 12,690 existing liferafts with SOLAS A packs and 2,552 lifeboats with international voyage packs (see table 9) for a total of 15,242 existing survival craft that are required to stock emergency water. We then estimated that 20 percent (100 percent of these survival craft ÷ 5 years) or 3,048 survival craft [(12,690 liferafts \times 20 percent) + $(2,552 \text{ lifeboats} \times 20 \text{ percent})$ will replace their emergency water annually. Additionally, all 31 new lifeboats with international packs and 136 new liferafts with SOLAS A packs (see table 10) are required to buy emergency water. We summed these totals to get 3,215 survival craft that will need to purchase emergency water on an annual basis (3,048 existing survival craft + 31 new lifeboats + 136 new liferafts). Table 21 presents these cost savings.

In Years 6 through 10, there will be more cost savings, because vessels will have entirely replaced their survival craft equipment by Year 6, as described earlier in this rule. Therefore, we estimate an annual cost savings of about \$192,774 [3,382 survival craft (3,215 + 167 new craft) × 19 people per survival craft × 3 liters of water × - \$1 cost savings] for survival craft with SOLAS A packs. Table 22 presents these cost savings.

²⁹We estimate the cost savings for only one can opener because the use of a jackknife will only fulfill the replacement requirement for one can opener.

³⁰ We calculated this by taking the average of 10 can opener products on the market that meet ISO 18813 requirements. The Coast Guard will now require that can openers meet the standards of ISO 18813.

³¹We calculated this by taking the average of 14 Coast Guard-approved emergency drinking water products on the market.

 $^{^{32}}$ We calculated this by taking the average of 14 available emergency drinking water products on the market that were compliant with ISO 18813 only.

³³ To calculate this, we took the average of emergency drinking water prices that were Coast Guard-approved and subtracted them from emergency drinking water prices that need only meet the ISO standard.

³⁴ We calculated this by taking the average of the survival craft capacity for all survival craft. We retrieved this data from the MISLE database in November 2020.

TABLE 21—TOTAL COST SAVINGS FOR COAST GUARD APPROVAL FOR REDUCED PRICES IN EMERGENCY WATER FOR SOLAS A PACKS IN YEARS 1 THROUGH 5

Years 1 through 5	Total life- rafts and lifeboats	New life- boats and liferafts	Total survival craft	Person per life saving craft	Liters of water required	Total water needed in liters	Cost of water	Total cost savings
	(a)	(b)	(c) = (a) + (b)	(d)	(e)	$(f) = (c) \times (d) \times (e)$	(g)	$ (h) = (g) \times (f) $
Baseline	3,048 3,048	167 167	3,215 3,215	19 19 0	3 3 0	183,255 183,255 0	\$4 3 -1	\$733,020 549,765 - 183,255

TABLE 22—TOTAL COST SAVINGS FOR COAST GUARD APPROVAL FOR REDUCED PRICES IN EMERGENCY WATER FOR SOLAS A PACKS IN YEARS 6 THROUGH 10

Years 6 through 10	Total life- rafts and lifeboats	New life- boats and liferafts	Total survival craft	Person per life saving craft	Liters of water required	Total water needed in liters	Cost of water	Total cost savings
	(a)	(b)	(c) = (a) + (b)	(d)	(e)	(f) = (c) × (d) × (e)	(g)	(h) = (g) × (f)
Baseline Post-Regulatory Change	3,215 3,215	167 167	3,382 3,382	19 19 0	3 3 0	192,774 192,774 0	\$4 3 -1	\$771,096 578,322 - 192,774

Note: Totals may not sum due to rounding.

We used the same methodology when calculating the number of SOLAS A packs in Years 1 through 10 of implementation to estimate the total costs savings for survival craft with SOLAS B packs. There are a total of 283 existing lifeboats with SOLAS B packs (see table 9). We estimate that 20 percent of these survival craft or 57 survival craft (283 lifeboats × 20 percent) will replace their emergency water annually. Additionally, all 2 new lifeboats with SOLAS B packs are

required to buy emergency water, for a total of 59 survival craft (57 lifeboats + 2 new lifeboats) purchasing emergency water in Years 1 through 5. In Years 6 through 10, the number of existing lifeboats will increase by 2 to account for the new vessels that will be built in Years 1 through 5 (59) for a total of 61 survival craft (59 existing survival craft + 2 new lifeboats).

The cost savings for survival craft with SOLAS B packs purchasing emergency water will be approximately \$1,682 (59 survival craft \times 19 people per survival craft \times 1.5 liters of water \times - \$1 cost savings) in Years 1 through 5 and approximately \$1,739 (61 survival craft \times 19 people per survival craft \times 1.5 liters of water \times - \$1 cost savings) in Years 6 through 10. Table 23 presents these cost savings in Years 1 through 5 of implementation, and table 24 presents these cost savings in Years 6 through 10 of implementation.

TABLE 23—TOTAL COST SAVINGS FOR COAST GUARD APPROVAL FOR REDUCED PRICES IN EMERGENCY WATER FOR SOLAS B PACKS IN YEARS 1 THROUGH 5

Water Years 1–5	New liferafts	New lifeboats	Total new survival craft	Person per life saving craft	Liters of water required	Total water	Cost	Total cost savings
	(a)	(b)	(c) = (a) + (b)	(d)	(e)	$ (f) = [(c) \times (d) \times (e)] $	(g)	(h) = (f) × (g)
Baseline Post-Regulatory Change	57 57 0	2 2 0	59 59 0	19 19 0	1.5 1.5 0	1,682 1,682 0	\$4 3 -1	\$6,728 5,046 -1,682

Note: Totals may not sum due to rounding.

TABLE 24—TOTAL COST SAVINGS FOR COAST GUARD APPROVAL FOR REDUCED PRICES IN EMERGENCY WATER FOR SOLAS B PACKS IN YEARS 6 THROUGH 10

Water years 6–10	New liferafts	New lifeboats	Total new survival craft	Person per life saving craft	Liters of water required	Total water	Cost	Total cost savings
	(a)	(b)	(c) = (a) + (b)	(d)	(e)	$ (f) = [(c) \\ \times (d) \times (e)] $	(g)	(h) = (f) × (g)
Baseline Post-Regulatory Change	59 59 0	2 2 0	61 61 0	19 19 0	1.5 1.5 0	1,739 1,739 0	\$4 3 -1	\$6,956 5,217 -1,739

Note: Totals may not sum due to rounding.

Table 25 presents the total annualized cost savings to vessel owners and

operators from removing Coast Guard approval requirements for emergency

water. The Coast Guard estimates an annualized cost savings of about

\$188,923 with a 7-percent discount rate (\$189,372 with 3-percent discount rate).

TABLE 25—TOTAL COST SAVINGS TO VESSELS FROM REMOVING COAST GUARD APPROVAL FOR REDUCED PRICES IN EMERGENCY WATER

	Cost savings for vessels	Cost savings for vessels	Total cost	Annualized c	ost savings
Year	with SOLAS A with SOLAS B packs packs		savings	3%	7%
(a)	(b)	(c)	(d) = (b) + (c)	(e) = (d) ÷ 1.03 ^(a)	(f) = (d) ÷ 1.07 ^(a)
1	\$183,255	\$1,682	\$184,937	\$179,550	\$172,838
2	- 183,255	- 1,682	– 184,937	- 174,321	– 161,531
3	- 183,255	- 1,682	– 184,937	- 169,244	-150,964
4	- 183,255	- 1,682	- 184,937	- 164,314	-141,088
5	- 183,255	- 1,682	- 184,937	- 159,528	- 131,858
6	- 192,774	- 1,739	- 194,513	- 162,902	-129,612
7	- 192,774	-1,739	- 194,513	- 158,157	- 121,133
8	- 192,774	-1,739	- 194,513	- 153,550	-113,208
9	- 192,774	- 1,739	- 194,513	- 149,078	-105,802
10	- 192,774	-1,739	- 194,513	- 144,736	-98,881
Total	- 1,880,145	- 17,105	-1,897,250	1,615,380	-1,326,915
Annualized				- 189,372	- 188,923

Note: Totals may not sum due to rounding.

First-Aid Kits

The Coast Guard is modifying the requirements for first-aid kits so that all first-aid kits in survival craft must meet the standards outlined in ISO 18813. In addition to removing the testing requirements for the kits, this change

modifies the required contents of firstaid kits by removing the requirements for some items, adding additional items, or changing the number of mandatory items. Since items within the kits expire and need to be replaced, the change impacts both new and existing vessels, including small passenger vessels described in the *Subchapters K and T* section in this preamble. Table 26 highlights these differences in the first-aid kit requirement. Due to the differences in the first-aid kits, we estimate the cost of purchasing each of the individual items in the kit.

TABLE 26—CROSSWALK OF FIRST-AID KIT CONTENT REQUIREMENTS

		Number of items required	
Item	Lifeboats and rescue boat requirements under § 160.041–4	Liferaft and IBA requirements under § 160.054–4	ISO 18813 requirements
Adhesive Plasters Ammonia Inhalants Analgesic Medication Antiseptic Preparations Burn Preparations Compression Bandage (for wounds). Compression Bandage (for securing splints, dressings, etc.). Eye Dressing Packet Instructions Sterile Gauze Compress Tourniquet, with forceps, scissors and pins. Triangle Bandage Waterproof Container Wire Splint	10	10 iodine swabs	20 bandages in assorted sizes. 0. 48 doses. 10 applications. 12 applications. 10 sterile bandages in assorted sizes. 4 meters (4.4 yards) of adhesive elastic bandage. 0. 1. 2. 0. 2. 1. 0.

First-Aid Kits for Lifeboats and Rescue Boats

We estimate that new vessels with lifeboats or rescue boats will have a cost savings as a result of the changes to first-aid kits, because we estimate that first-aid kits that meet the standard are \$41 less expensive than Coast Guardapproved kits under approval series 160.041. We estimate that a total of 64 new lifeboats and rescue boats will purchase a first-aid kit each year for a total costs savings of approximately \$2,624 (64 survival craft \times \$41 cost savings).

The Coast Guard is not requiring existing vessels to replace their current kits; however, existing vessels must replace medication and ointments within the kits by their expiration date.

Currently, vessels must replace their iodine swabs, pain relief medication, and eye ointment, which we estimate costs about \$19 per kit.35 We calculated the cost per kit by taking the average price for 10 different iodine swab products, 12 different pain relief medication, and 8 different eye ointments. Under this rule, these vessels will no longer have to replace eye ointment, and will need to replace fewer doses of pain relief medication. Additionally, vessel operators will be able to replace iodine swabs with less expensive antiseptic preparation. However, under this rule, vessels will incur an additional cost from replacing the burn cream in the kits, as required by ISO 18813 shown in table 26. We estimate the cost of replacing these items to be \$19, meaning the change is cost-neutral to existing vessels with lifeboat first-aid kits.36

First-Aid Kits for Liferafts and IBAs

We estimate that first-aid kits that meet the requirements of ISO 18813 will be, on average, \$1 less expensive than the Coast Guard-approved kits for

liferafts and IBAs.³⁷ All 218 new liferafts and all 25 new IBAs will need to be equipped with the kits each year for an annual cost savings of \$243 (243 survival craft \times -\$1 cost saving).³⁸ Liferaft first-aid kits are sealed in plastic bags, and most drugs expire within a 2to 3-year timeframe. Vessel owners and operators have to replace the entire firstaid kit with a brand new kit after using even one item. Once the packaging for the kit is opened, the majority of items in it will have the same expiration date, not just the individual item.39 Therefore, the Coast Guard estimates that vessels will replace the items in their first-aid kits once they have expired, every 2.5 years (average of 2 and 3 years), and this process occurs during the annual servicing at an approved servicing facility.

We calculate that 40 percent (1 replacement every 2.5 years) of vessels will replace these items annually. Forty percent of all existing 2,612 IBAs and 22,377 liferafts [table 9 (sum of the totals for SOLAS A and SOLAS B for inflatable liferafts columns)] is 9,996

survival craft [(2,612 IBAs \times 40 percent) + $(22,377 \text{ liferafts} \times 40 \text{ percent})$]. Beginning in Year 3, the new survival craft from Year 1 will need to replace their kits for a total of 10,239 survival craft (9,996 existing survival craft + 243 survival craft built in Year 1). In Year 4, the new survival craft from Year 2 will need to replace their kits, but those from Year 1 will not need to do this, since they will have replaced their kits in the prior year. Therefore, the total needing to replace first-aid kits will still be 10,239 survival craft (9,996 existing survival craft + 243 survival craft built in Year 2). In Year 5, the survival craft built in Year 1 and Year 3 will replace their kits for a total of 10,482 survival craft (9,996 existing survival craft + 243 survival craft built in Year 1 + 243 survival craft built in Year 3). This pattern continues over the 10-year analysis period. In conclusion, we estimate the total annualized cost savings from removing Coast Guard approval for liferaft first-aid kits will be \$10,660 with a 7-percent discount rate as shown in table 27.

TABLE 27—TOTAL COST SAVINGS TO VESSELS FROM REMOVING COAST GUARD APPROVAL REQUIREMENTS FOR FIRST-AID KITS IN LIFERAFTS AND IBAS

		Cost sa	avings for replace	ment kits		Annualized c	ost savings
Year	Cost savings to new vessels	Total survival craft replacing kits	Cost savings for replacement	Total cost savings for replacements	Total cost savings	3%	7%
(a)	(b)	(c)	(d)	$(e) = (c) \times (d)$	(f) = (b) + (e)	$(g) = (f) \div 1.03^{(a)}$	$(h) = (f) \div 1.07^{(a)}$
1	-\$243	9,996	-\$1	- \$9,996	- \$10,239	- \$9,941	- \$9,569
2	- 243	9,996	Ψ1 — 1	- 9,996	- 10.239	- 9,651	- 8,943
2	- 243	10,239	-1	- 10,239	- 10,482	- 9,593	-8,556
3	-243	10,239	_1	- 10,239	- 10.482	- 9,313	- 7,997
4	- 243 - 243	10,482	-1	- 10,239 - 10,482	- 10,462 - 10,725	- 9,313 - 9,251	- 7,647 - 7,647
5	- 243 - 243	10,482	- I - 1	· '	- 10,725 - 10,725	- 9,251 - 8,982	- 7,047 - 7,147
0		,	= 1 = 1	- 10,482	,	,	,
/	-243	10,725		- 10,725	-10,968	-8,918	-6,830
8	-243	10,725	-1	- 10,725	- 10,968	-8,658	-6,383
9	-243	11,968	-1	- 11,968	- 11,211	-8,592	-6,098
10	-243	11,968	-1	- 11,968	- 11,211	-8,342	-5,699
Total						-91,242	-74,870
Annualized						- 10,696	- 10,660

Note: Totals may not sum due to rounding.

First-Aid Kits for Small Passenger Vessels (Subchapter K and Subchapter T)

This final rule will also remove Coast Guard approval requirements for firstaid kits aboard small passenger vessels, which the Coast Guard regulates under subchapters K and T. Small passenger vessels are currently required to have first-aid kits approved under approval series 160.041; therefore, we used the same cost savings estimates for replacing first-aid kits in the section titled First-Aid Kits for Lifeboats and Rescue Boats. This comes to \$41 per first-aid kit. The Coast Guard applied

these estimates to small passenger vessels, which will no longer need Coast Guard approval for the first-aid kits aboard the vessels themselves. We estimate that there will be 40 new small passenger vessels every year (see table 5). All of the 40 new passenger vessels will need to be equipped with first-aid

³⁵ ISO 18813 uses the specific language of Analgesic and Ophthalmic when describing the medication in the first-aid kits. Refer to the appendix titled "Appendix B: Product Prices" in the docket folder for more information on product prices for these items that comprise the first-aid kit.

 $^{^{36}\,\}rm The$ Coast Guard used the same price estimation for the average cost of these items as the cost it would take to replace them.

³⁷ The Coast Guard took the average price of six Coast Guard-approved first-aid kits and subtracted it from an average of six first-aid kits that met ISO standards.

 $^{^{38}}$ There are 222 liferafts affected by this rule, but those requiring SOLAS A and B packs (218 liferafts) will be required to have first-aid kits.

³⁹We contacted a liferaft servicing firm to determine how the expired items in liferaft and lifeboat first-aid kits are replaced.

kits each year, for an annual cost savings of \$1,640.

Total Cost Savings to Vessel Owners and Operators

Table 28 presents the annual undiscounted total cost savings to vessel

owners and operators by equipment type, and table 29 presents the total annualized cost savings. We estimate the total undiscounted costs savings to vessel owners and operators at \$2.85 million over a 10-year period of analysis, with an annualized total cost savings of about \$284,481 discounted at 7 percent (\$284,966 with a 3-percent discount rate).

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Table :	28: Total C	Cost Savings	to Vessel Ov	vners and O	perators							
Year	Bilge pump	Compass	First-Aid Kits for Lifeboats	First-Aid Kits for Liferafts	Fishing Kit	Hatchet	Jackknife*	Mirrors	First-Aid Kits for Subchapter K & T	Sea Anchor	Water	Total Cost Savings
1	-\$2,541	-\$22,400	-\$2,624	-\$10,239	-\$341	-\$528	-\$2,640	-\$1,400	-\$1,640	-\$50,784	-\$184,937	-\$280,074
2	-\$2,541	-\$22,400	-\$2,624	-\$10,239	-\$341	-\$528	-\$2,640	-\$1,400	-\$1,640	-\$50,784	-\$184,937	-\$280,074
3	-\$2,541	-\$22,400	-\$2,624	-\$10,482	-\$341	-\$528	-\$2,640	-\$1,400	-\$1,640	-\$50,784	-\$184,937	-\$280,317
4	-\$2,541	-\$22,400	-\$2,624	-\$10,482	-\$341	-\$528	-\$2,640	-\$1,400	-\$1,640	-\$50,784	-\$184,937	-\$280,317
5	-\$2,541	-\$22,400	-\$2,624	-\$10,725	-\$341	-\$528	-\$2,640	-\$1,400	-\$1,640	-\$50,784	-\$184,937	-\$280,560
6	-\$2,541	-\$22,400	-\$2,624	-\$10,725	-\$341	-\$528	-\$2,640	-\$1,400	-\$1,640	-\$50,784	-\$194,513	-\$290,136
7	-\$2,541	-\$22,400	-\$2,624	-\$10,968	-\$341	-\$528	-\$2,640	-\$1,400	-\$1,640	-\$50,784	-\$194,513	-\$290,379
8	-\$2,541	-\$22,400	-\$2,624	-\$10,968	-\$341	-\$528	-\$2,640	-\$1,400	-\$1,640	-\$50,784	-\$194,513	-\$290,379
9	-\$2,541	-\$22,400	-\$2,624	-\$11,211	-\$341	-\$528	-\$2,640	-\$1,400	-\$1,640	-\$50,784	-\$194,513	-\$290,622
10	-\$2,541	-\$22,400	-\$2,624	-\$11,211	-\$341	-\$528	-\$2,640	-\$1,400	-\$1,640	-\$50,784	-\$194,513	-\$290,622
Total	-\$25,410	-\$224,000	-\$26,240	-\$107,250	-\$3,410	-\$5,280	-\$26,400	-\$14,000	-\$16,400	-\$507,840	-\$1,897,250	-\$2,853,480

Note: Totals may not sum due to rounding.

*Includes the estimated cost savings from both removing Coast Guard approval for jackknives and allowing vessels to replace knives with jackknives and the cost savings of no longer needing one can opener for SOLAS A liferafts.

TABLE 29—ANNUALIZED COST SAVINGS TO VESSEL OWNERS AND OPERATORS

Warn	T. A. I A	Annualized o	ost savings
Year	Total cost savings	3%	7%
(a)	(b)	(c) = (b) \div 1.03 ^(a)	(d) = (b) \div 1.07 ^(a)
1	- \$280,074	- \$271,917	- \$261,751
2	-\$280,074	-\$263,997	-\$244,627
3	-\$280,317	-\$256,530	-\$228,822
4	- \$280,317	-\$249,058	-\$213,852
5	-\$280,560	-\$242,014	-\$200,035
6	-\$290,136	-\$242,984	-\$193,330
7	-\$290,379	-\$236,105	-\$180,833
8	-\$290,379	-\$229,228	-\$169,003
9	-\$290,622	-\$222,738	-\$158,079
10	-\$290,622	-\$216,250	-\$147,737
Total	-\$2,853,480	-\$2,430,819	-\$1,998,072
Annualized		- \$284,966	- \$284,481

Total Cost Savings to Industry

Table 30 presents the total annualized costs savings to industry over the 10-

year period of analysis. At a 7-percent discount rate, the cost savings is approximately \$303,805.

TABLE 30—TOTAL ANNUALIZED COST SAVINGS TO INDUSTRY

W	Total cost savings	Total cost savings	Takal as ak a sada sa	Annualized cost savings			
Year	to manufacturers *	to vessels**	Total cost savings	3%	7%		
(a)	(b)	(c)	(d) = (b) + (c)	(e) = (d) \div 1.03 ^(a)	$(f) = (d) \div 1.07^{(a)}$		
1	-\$19,324	-\$280,074	-\$299,398	-\$290,678	-\$279,811		
2	- 19,324	-280,074	-299,398	-282,211	-261,506		
3	- 19,324	-280,317	-299,641	-274,214	-244,596		
4	- 19,324	-280,317	-299,641	-266,227	-228,595		
5	- 19,324	-280,560	-299,884	-258,683	-213,813		
6	- 19,324	-290,136	-309,460	-259,168	-206,206		
7	- 19,324	-290,379	-309,703	-251,817	-192,867		
8	- 19,324	-290,379	-309,703	-244,482	-180,250		
9	- 19,324	-290,622	-309,946	-237,548	-168,590		
10	- 19,324	-290,622	-309,946	-230,629	- 157,561		
Total	- 193,240	-2,853,480	-3,046,720	-2,595,657	-2,133,796		
Annualized				-304,290	- 303,805		

Note: Totals may not sum due to rounding.

Federal Government Cost Savings

We estimate that this rule will reduce costs to the Federal Government, since the Coast Guard will no longer review COA applications, application renewals, or inspection reports for the equipment that is subject to this rule. The Coast Guard does not anticipate that this rule will generate any cost savings from vessels inspections, as this rule does not modify any inspection requirements.

Equipment Approval

In addition to generating a cost savings to industry by removing COA

application requirements, this rule will also create a cost savings to the Federal Government, as Coast Guard staff will no longer review new COA applications and renewals. We estimate that it takes 24 hours of a GS–14's time to review each new application and 4 hours to review each renewal.⁴⁰ We estimate the cost of reviewing a new application at \$2,672 (rounded) per applicant (24 hours × \$111.34), and the cost for

reviewing a renewal application at \$445(rounded) per renewal (4 hours × \$111.34). In table 31, the cost of reviewing a new application is captured in column (b) and the cost of a renewal application is captured in column (d). In total, we estimate the Federal Government will save \$4,735 each year, due to this rule removing the requirements of having to review COA applications.

^{*}Table 19.

^{**} Table 28.

⁴⁰ This is based on information from the subchapter Q ICR. For the wage rate, \$111.34, please see the *Wages* section of this RA.

TABLE 31—ANNUAL COST SAVINGS TO FEDERAL GOVERNMENT FOR NO LONGER HAVING TO REVIEW NEW AND RENEWAL CERTIFICATE OF APPROVAL APPLICATIONS

	Approval	New app	olications	Renewal a	pplications	Total change
Equipment	Approval series	Total number of applications	Total cost	Total number of applications	Total cost	in cost = total cost savings
		(a)	(b) = (a) × [-\$2,672]	(c)	(d) = (c) × [-\$445]	(e) = (b) + (d)
Bilge pump	160.044	0.09	-\$240	0.60	-\$267	- \$507
Compass	160.014	0.09	-240	0.60	-267	-507
First-aid kit for Lifeboats	160.041	0.15	-401	1	-445	-846
First-aid kit for Liferafts	160.054	0.15	-401	1	-445	-846
Fishing kit	160.061	0.03	-80	0.20	-89	- 169
Hatchet	160.013	0.03	-80	0.20	-89	- 169
Jackknife	160.043	0.03	-80	0.20	-89	- 169
Mirror, Signaling	160.020	0.06	- 160	0.4	-178	-338
Sea anchor	160.019	0.03	-80	0.20	-89	– 169
Water	160.026	0.18	-481	1.20	-534	– 1015
Total			-2,243		-2,492	-4,735

Laboratory Inspections

The Coast Guard currently requires manufacturers of some equipment to submit an annual report with the results of laboratory inspections, allowing the Coast Guard to ensure the production stock of the equipment will be identical to those originally tested and approved by the Coast Guard. This rule removes this reporting requirement for equipment that is now self-certified by the manufacturer. We were unable to obtain data about the costs related to laboratory inspections.

We estimate that it takes approximately 2 hours of a GS–14

senior engineer's time to review each report, costing \$223 (2 hours \times \$111.34). Table 32 presents the total annual cost saving to the Federal Government for no longer having to review laboratory inspection reports. We estimate these cost savings will be \$5,352 per year.

TABLE 32—ANNUAL FEDERAL GOVERNMENT COST SAVINGS FOR NO LONGER HAVING TO REVIEW LABORATORY INSPECTION RECORDS

Fauinment	Approval series	Baseline scenario		Post-regulatory scenario		Total change in cost = total
Equipment		Total products	Total cost	Total products	Total cost	cost savings
		(a)	(b) = (a) × \$223	(c)	(d) = (c) × \$223	(e) = (d) - (b)
Bilge pump	160.044	3	\$669	0	\$0	-\$669
Compass	160.014	3	669	0	0	-669
First-aid kit for Lifeboats	160.041	5	1,115	0	0	- 1,115
First-aid kit for Liferafts	160.054	5	1,115	0	0	- 1,115
Mirror, Signaling	160.020	2	446	0	0	-446
Water	160.026	6	1,338	0	0	-1,338
Total		24	5,352	0	0	5,352

Note: Totals may not sum due to rounding.

Total Federal Government Savings

Table 33 presents the total annual cost savings to the Federal Government. In

total, the Coast Guard estimates this rule to generate a cost savings of approximately \$10,087 per year.

TABLE 33—TOTAL ANNUAL COST SAVINGS TO THE FEDERAL GOVERNMENT

Equipment	Approval series	New applications avoided	Renewed applications avoided	Avoided inspection reports	Total cost savings
		(a)	(b)	(c)	(d) = (a) + (b) + (c)
Bilge pump Compass First-aid kit for Lifeboats First-aid kit for Liferafts	160.044 160.014 160.041 160.054	- \$240 - 240 - 401 - 401	-\$267 -267 -445 -445	-\$669 -669 -1,115 -1,115	-\$1,176 -1,176 -1,961 -1,961

TABLE 33—TOTAL ANNUAL COST SAVINGS TO THE FEDERAL GOVERNMENT—Continued

Equipment	Approval series	New applications avoided	Renewed applications avoided	Avoided inspection reports	Total cost savings
		(a)	(b)	(c)	(d) = (a) + (b) + (c)
Fishing kit	160.061 160.013 160.043	-80 -80 -80	- 89 - 89 - 89	0 0 0	- 169 - 169 - 169
Mirror, Signaling Sea anchor Water	160.020 160.019 160.026	- 160 - 80 - 481	- 178 - 89 - 534	- 446 0 - 1.338	-784 -169 -2,353
Total		-2,243	-2,492	- 5,352	-10,087

Change in Safety

Many of the current Coast Guard type approval requirements for survival craft equipment were developed in the 1950s and 1960s and have not been significantly updated since they were initially published. Upon a thorough review of these requirements, Coast Guard enforcement procedures, current maritime industry practice, and the availability of new international standards, we have determined that the

additional scrutiny of the Coast Guard type approval does not increase or decrease the safety for the equipment subject to this rule. For these nine types of survival craft equipment, the current Coast Guard type approval requirements are outdated and overly prescriptive. Therefore, the Coast Guard anticipates that by having equipment meet consensus standards, as opposed to Coast Guard standards, there will be no decrease in the level of safety in the maritime environment.

No Cost Changes

This rule will also implement several changes with no cost impacts. The vast majority of these changes are the result of modifying the current lifeboat equipment requirements for sailing school vessels as stated in § 169.527 to align them with the requirements stated in § 199.175. Table 34 summarizes these changes.

TABLE 34—SUMMARY OF REGULATORY CHANGES WITH NO COST IMPACTS

Equipment	CFR subpart/ section(s)	Affected population	Changes	Basis for no cost
Bailer	§ 169.529(a)	New U.Sflagged Sailing School Vessels with Life- boats.	Removes requirements that bailers in lifeboats on sailing school vessels meet the requirements of § 169.529(a) and instead, they must meet the requirements of § 199.175(b)(1).	This is an administrative change that allows the Coast Guard to consolidate its survival craft equipment standards, and the requirements of §§ 169.529(a) and 199.175(b)(1) are identical.
Boathooks	§ 169.529(c)	New U.Sflagged Sailing School Vessels with Life- boats.	Removes requirements that boathooks in lifeboats on sailing school vessels meet the prescribed design requirements of § 169.529(c) and instead, they must meet the requirements of § 199.175(b)(3) and be designed to minimize the possibility of damage.	Sections 169.529(c) and 199.175(b)(3) set different standards for boathooks; however, only new U.Sflagged sailing school vessels will be impacted by the change, and the Coast Guard estimates that no new U.Sflagged sailing school vessels will be built during the analysis period.
Can Openers.	§ 199.175(b)(5)	All U.Sflagged Vessels with Lifeboats or Liferafts with SOLAS A packs.	Can openers must meet the standards of ISO 18813.	ISO 18813 requires that can openers in liferafts be of the safety type. The Coast Guard estimates that all liferafts are currently equipped with either a safety can opener or a can opener within the jackknife; therefore, this change poses no additional cost to industry.
Cover, Pro- tecting.	§ 169.529(II)	New U.Sflagged Sailing School Vessels with Life- boats.	Fully enclosed lifeboats on sailing school vessels do not need to be equipped with a cover.	Only new U.Sflagged sailing school vessels will be impacted by the change, and the Coast Guard estimates that no new U.Sflagged sailing school vessels will be built during the analysis period. In addition, fully enclosed lifeboats do not require a cover; therefore, it is likely they are not equipped with one under the baseline.

TABLE 34—SUMMARY OF REGULATORY CHANGES WITH NO COST IMPACTS—Continued

Equipment	CFR subpart/ section(s) Affected population Changes		Basis for no cost	
Ditty Bag	§ 169.529(f)	New U.Sflagged Sailing School Vessels with Life- boats.	Motor-propelled lifeboats on sailing school vessels no longer need to carry a ditty bag.	Only new U.Sflagged sailing school vessels will be impacted by the change, and the Coast Guard estimates that no new U.Sflagged sailing school vessels will be built during the analysis period.
Drinking Cups.	§ 169.529(g)	New U.Sflagged Sailing School Vessels with Life- boats.	Removes requirements that drinking cups in lifeboats on sailing school vessels meet the requirements of § 169.529(g) and instead, they must meet the requirements of § 199.175(b)(8).	This is an administrative change that allows the Coast Guard to consolidate its survival craft equipment standards, and the requirements of §§ 169.529(g) and 199.175(b)(8) are identical.
Fire Extinguisher.	§ 169.529(h), § 199.175(b)(9)	All New U.Sflagged Vessels with IBAs, Liferafts, Lifeboats, or Rescue Boats.	Updates fire extinguisher rating names from B–C, size II to 40–B to match other regulatory text in title 46 of the CFR.	This change does not require fire extinguishers meet any different requirements as laid out in the final rule, "Harmonization of Standards for Fire Protection, Detection and Extinguishing Equipment" (81 FR 482200 July 22, 2016), only that they have a label. A review of portable marine fire extinguishers found that both the Coast Guard and UL ratings are currently provided for each product.
First-Aid Kits.	§ 121.710 § 160.010– 3(e)(7)(ii) Subpart 160.041 Subpart 160.054 § 160.151–21(h) § 169.529(i) § 184.710 § 199.050(c) § 199.175(b)(10)	All U.Sflagged Vessels with IBAs, Liferafts with a SOLAS A or B pack, Life- boats, or Rescue Boats. All small passenger ves- sels in Subchapters K and T.	All medicinal products within the first- aid kits must use active ingredients that conform to OTC drug regula- tions set out in 21 CFR part 330.	The Coast Guard estimates that, under the baseline, all medicinal products meet U.S. OTC drug standards. The Coast Guard did an extensive inquiry to ensure that the medicinal products were FDA compliant.
Flashlights	§ 169.529(j)	New U.Sflagged Sailing School Vessels with Life- boats.	Removes requirement that flashlights in lifeboats on sailing school vessels meet the prescribed design requirements of § 169.529(j) and instead, they must meet the requirements of § 199.175(b)(12) and be constructed and marked according to the American Society for Testing and Materials' ASTM F1014 standard already incorporated by reference in that section.	This is an administrative change that allows the Coast Guard to consolidate its survival craft equipment standards.
Heaving Lines.	§ 169.529(I)	New U.Sflagged Sailing School Vessels with Life- boats.	Removes requirement that heaving lines on lifeboats on sailing school vessels meet the requirements of § 169.529(l), and instead, they must meet the requirements of § 199.175(b)(14).	This is an administrative change that allows the Coast Guard to consolidate its survival craft equipment standards, and the requirements of §§ 169.529(l) and 199.175(b)(14) are identical.
Ladder	§ 169.529(n)	New U.Sflagged Sailing School Vessels with Life- boats.	Removes requirement that ladders on lifeboats on sailing school vessels meet the requirements of § 169.529(n), and instead, they must meet the requirements of § 199.175(b)(18).	This is an administrative change that allows the Coast Guard to consolidate its survival craft equipment standards, and the requirements of §§ 169.529(n) and 199.175(b)(18) are identical.
Lanterns	§ 169.529(o)	New U.Sflagged Sailing School Vessels with Life- boats.	Removes requirement that lifeboats on sailing school vessels carry lanterns.	Only new U.Sflagged sailing school vessels are impacted by the change, and the Coast Guard estimates that no new U.Sflagged sailing school vessels will be built during the analysis period.
Lifelines	§ 169.529(p)	New U.Sflagged Sailing School Vessels with Life- boats.	Removes lifeline standards from § 169.529(p).	This is an administrative change, as lifelines are not survival craft equipment and are, instead, regulated as part of the lifeboat design requirements under § 160.135–7.

TABLE 34—SUMMARY OF REGULATORY CHANGES WITH NO COST IMPACTS—Continued

Equipment	CFR subpart/ section(s)	Affected population	Changes	Basis for no cost
Life Pre- servers.	§ 169.529(q)	New U.Sflagged Sailing School Vessels with Life- boats.	Removes requirement that lifeboats on sailing school vessels carry two additional life preservers in their lifeboat.	Only new U.Sflagged sailing school vessels will be impacted by the change, and the Coast Guard estimates that no new U.Sflagged sailing school vessels will be built during the analysis period.
Lockers	§ 169.529(r)	New U.Sflagged Sailing School Vessels with Life- boats.	Removes requirement that lifeboats on sailing school vessels have lockers for the storage of small items.	Only new U.Sflagged sailing school vessels will be impacted by the change, and the Coast Guard estimates that no new U.Sflagged sailing school vessels will be built during the analysis period.
Mast and Sail.	§ 169.529(s)	New U.Sflagged Sailing School Vessels with Life- boats.	Clarifies that motor-propelled lifeboats on sailing school vessels do not need to carry a mast or sails.	Only new U.Sflagged sailing school vessels will be impacted by the change, and the Coast Guard estimates that no new U.Sflagged sailing school vessels will be built during the analysis period. In addition, motorized boats do not require a mast or sails; therefore, they are not equipped with them under the baseline.
Matches	§ 169.529(t)	New U.Sflagged Sailing School Vessels with Life- boats.	Removes requirement that lifeboats on sailing school vessels carry matches.	Only new U.Sflagged sailing school vessels will be impacted by the change, and the Coast Guard estimates that no new U.Sflagged sailing school vessels will be built during the analysis period.
Oars	§ 169.529(v)	New U.Sflagged Sailing School Vessels with Life- boats.	Removes requirement that oars on lifeboats on sailing school vessels meet the requirements of § 169.529(v), and instead, they must meet the requirements of § 199.175(b)(20). In addition, the Coast Guard is modifying the number of required oars from four rowing and one steering, to the number required by the manufacturer.	This is an administrative change that allows the Coast Guard to consolidate its survival craft equipment standards, and the requirements of §§ 169.529(v) and 199.175(b)(20) are identical. There are no cost savings because there are no sailing school vessels with lifeboats. In addition, only new U.Sflagged sailing school vessels will be impacted by the change, and the Coast Guard estimates that no new U.Sflagged sailing school vessels will be built during the analysis period.
Oil, Illu- minating.	§ 169.529(w)	New U.Sflagged Sailing School Vessels with Life- boats.	Removes requirement that lifeboats on sailing school vessels carry illuminating oil for lanterns.	Only new U.Sflagged sailing school vessels will be impacted by the change, and the Coast Guard estimates that no new U.Sflagged sailing school vessels will be built during the analysis period.
Oil, Storm	§ 169.529(x)	New U.Sflagged Sailing School Vessels with Life- boats.	Removes requirement that lifeboats on sailing school vessels carry storm oil to calm the seas.	Only new U.Sflagged sailing school vessels will be impacted by the change, and the Coast Guard estimates that no new U.Sflagged sailing school vessels will be built during the analysis period.
Painters	§ 169.529(y)	New U.Sflagged Sailing School Vessels with Life- boats.	Removes requirement that painters on lifeboats on sailing school vessels meet the requirements of § 169.529(y), and instead, they must meet the requirements of § 199.175(b)(21).	This is an administrative change that allows the Coast Guard to consolidate its survival craft equipment standards, and the requirements of §§ 169.529(n) and 199.175(b)(18) are identical.
Plug	§ 169.529(z)	New U.Sflagged Sailing School Vessels with Life- boats.	Removes plug standards from § 169.529(z).	This is an administrative change, as plugs are not survival craft equipment and are, instead, regulated as part of the lifeboat design requirements under § 160.135–7

TABLE 34—SUMMARY OF REGULATORY CHANGES WITH NO COST IMPACTS—Continued

Equipment	CFR subpart/ section(s)	Affected population	Changes	Basis for no cost
Provisions	Subpart 160.046	All manufacturers of Coast Guard-approved provisions.	Adds to the scope: emergency provisions approved to be carried in lifeboats and liferafts. These provisions meet the IMO recommendations for emergency food rations.	This is an administrative change, as this rule will update § 199.175(b)(22) and add regulatory text to subpart 160.046 stating that the provisions or food rations must comply with ISO 18813 paragraph 4.31, which is the same as the current standard.
Rowlocks	§ 169.529(bb)	New U.Sflagged Sailing School Vessels with Life- boats.	Removes requirement that rowlocks on lifeboats on sailing school vessels meet the requirements of § 169.529(bb) and instead, they must meet the requirements of § 199.175(b)(20).	This is an administrative change that allows the Coast Guard to consolidate its survival craft equipment standards, and the requirements of §§ 169.529(bb) and 199.175(b)(20) are identical.
Rudder and Till- er.	§ 169.529(cc)	New U.Sflagged Sailing School Vessels with Life- boats.	Removes rudder and tiller standards from § 169.529(cc), which state the rudder and tiller must be con- structed according to § 169.035–3(f).	This is an administrative change, as § 169.035–3(f) was removed previously from the CFR, and the section no longer exists.
Signals, Distress Floating Orange Smoke.	§ 169.529(ee)	New and Existing U.S flagged Sailing School Vessels with Lifeboats.	Removes requirement that distress floating orange smoke signals on lifeboats on sailing school vessels meet the requirements of § 169.529(ee), and instead, they must meet the requirements of § 199.175(b)(30).	The change will apply to both new U.Sflagged sailing school vessels with lifeboats, and existing sailing school vessels with lifeboats, as these vessels will have to replace their smoke signals after they expire. The Coast Guard estimates that no new U.Sflagged sailing school vessels will be built during the analysis period. In addition, there are no existing sailing school vessels with lifeboats; therefore, no existing vessels will be impacted by the change.
Signals, Distress Red Hand Flare.	§ 169.529(ff)	All U.Sflagged Sailing School Vessels with Life- boats.	Removes requirement that distress red hand flare signals on lifeboats on sailing school vessels meet the requirements of § 169.529(ff), and instead, they must meet the requirements of § 199.175(b)(31).	The change will apply to both new U.Sflagged sailing school vessels with lifeboats, and existing sailing school vessels with lifeboats, as these vessels will have to replace their smoke signals after they expire. The Coast Guard estimates that no new U.Sflagged sailing school vessels will be built during the analysis period. In addition, there are no existing sailing school vessels with lifeboats; therefore, no existing vessels will be impacted by the change.
Signals, Distress Red Para- chute Flare.	§ 169.529(gg)	All U.Sflagged Sailing School Vessels with Life- boats.	Removes requirement that distress red parachute flares on lifeboats on sailing school vessels meet the requirements of § 169.529(gg), and instead, they must meet the requirements of § 199.175(b)(32).	Change. The change will apply to both new U.Sflagged sailing school vessels with lifeboats and existing sailing school vessels with lifeboats, as these vessels will have to replace their smoke signals after they expire. The Coast Guard estimates that no new U.Sflagged sailing school vessels will be built during the analysis period. In addition, there are no existing sailing school vessels with lifeboats; therefore, no existing vessels will be impacted by the change.
Table of Life- saving Signals.	§ 169.529(mm)	New U.Sflagged Sailing School Vessels with IBAs, Liferafts, Lifeboats, or Rescue Boats.	Removes requirement that table of lifesaving signals on lifeboats on sailing school vessels meet the requirements of § 169.529(mm), and instead, they must meet the requirements of § 199.175(b)(36).	This is an administrative change that allows the Coast Guard to consolidate its survival craft equipment standards, and the requirements of §§ 169.529(mm) and 199.175(b)(36) are identical.

	TABLE 34—SUMMANT OF NEGULATORY CHANGES WITH NO COST IMPACTS—CONTINUEU							
Equipment	CFR subpart/ section(s)	Affected population	Changes	Basis for no cost				
Tool Kit	§ 169.529(hh)	New U.Sflagged Sailing School Vessels with IBAs, Liferafts, Lifeboats, or Rescue Boats.	Removes requirements that toolkits on lifeboats on sailing school vessels meet the requirements of § 169.529(hh), and instead, they must meet the requirements of § 199.175(b)(38).	This is an administrative change that allows the Coast Guard to consolidate its survival craft equipment standards, and the requirements of §§ 169.529(hh) and 199.175(b)(38) are identical.				
Whistle	§ 169.529(jj)	New U.SFlagged Sailing School Vessels with IBAs, Liferafts, Lifeboats, or Rescue Boats.	Removes requirement that whistles on lifeboats on sailing school vessels meet the requirements of. § 169.529(jj), and instead, they must meet the requirements of § 199.175(b)(41).	This is an administrative change that allows the Coast Guard to consolidate its survival craft equipment standards, and the requirements of §§ 169.529(jj) and 199.175(b)(41) are identical.				

TABLE 34—SUMMARY OF REGULATORY CHANGES WITH NO COST IMPACTS—Continued

Total Cost Savings

Table 35 presents the total annualized cost savings of this final rule to both

industry and the Federal Government for the 10-year period of analysis. The Coast Guard estimates an annualized cost savings of approximately \$314,377 with a 3-percent discount rate, and \$313,892 with a 7-percent discount rate.

TABLE 35—TOTAL ANNUALIZED COST SAVINGS TO INDUSTRY AND FEDERAL GOVERNMENT

	Total cost savings to industry*	Total cost savings to federal government**	Total cost	Annualized cost savings	
Year			savings	3%	7%
(a)	(b)	(c)	(d) = (b) + (c)	(e) = (d) ÷ 1.03 ^(a)	$(f) = (d) \div 1.07^{(a)}$
1	-\$299,398	-\$10,087	- \$309,485	- \$300,471	-\$289,238
2	-299,398	-10,087	- 309,485	-291,719	-270,316
3	-299,641	- 10,087	- 309,728	- 283,445	-252,830
4	-299,641	- 10,087	-309,728	-275,189	-236,290
5	-299,884	- 10,087	- 309,971	-267,384	-221,005
6	-309,460	- 10,087	- 319,547	-267,616	-212,928
7	309,703	10,087	319,790	260,019	199,149
8	-309,703	- 10,087	-319,790	- 252,445	- 186,121
9	-309,946	- 10,087	- 320,033	- 245,279	– 174,077
10	-309,946	- 10,087	-320,033	-238,135	- 162,689
TotalAnnualized	-3,046,720	- 100,870	-3,147,590	-2,681,701 314,377	-2,204,643 313,892

Note: Totals may not sum due to rounding.

** Table 33.

Discussion of Alternatives

When creating this rule, the Coast Guard considered four alternatives, one of which was suggested by public comment. In this section, we examine how the cost of the rulemaking changes with each alternative.

Alternative 1: No Action

Using this alternative, the Coast Guard will accept the status quo and not replace the current approval requirements with an international consensus standard. This alternative will not harmonize Coast Guard standards with industry consensus standards, nor reduce the burden to industry. This will not incur approximately \$314,000 in annual cost savings with no estimated benefits.

Alternative 2: Preferred Alternative— Remove the Need for Coast Guard Approval

Using this alternative, the Coast Guard will implement the changes regarding the removal of Coast Guard approval standards. This will lead to an estimated \$314,000 in annual cost savings without any estimated reduction in benefits, as this analysis shows.

Alternative 3: Remove the Need for Coast Guard Approval and Marking Requirements

Under this alternative, the Coast Guard will implement the changes in the preferred alternative, but will, in addition, remove the requirement that equipment be marked to indicate it meets ISO 25862, ISO 17339, or ISO 18813. This will lead to an additional

annual cost savings of approximately \$397,433. We estimate this by multiplying 254,765 pieces of equipment by \$1.56 (allowing 0.06 hours × \$26 production rate per hour for the time and cost to mark each piece of equipment). This will lead to a total cost savings of \$711,433, which we calculated by adding the additional savings from no markings (\$397,433) to the total estimated cost savings of this rule, as shown in alternative 2 (\$314,000).

We rejected this alternative for the preferred alternative, since eliminating the markings will make it impossible for the Coast Guard to verify if equipment complies with regulations. This alternative could potentially lead to a decrease in safety, if vessel owners and operators purchased non- ISO-

^{*} Table 30.

compliant products that were not sufficiently safe or reliable for usage on board a survival craft. The potential for the additional burden on the Coast Guard to research and ascertain the compliance status of a piece of survival craft equipment could lead to much more significant costs than the current additional cost of \$397,433 from marking equipment.

Alternative 4: Require Manufacturers To Cover the Cost of a COA

The Coast Guard received a public comment suggesting that the manufacturers should cover the cost of COAs. We interpreted this comment as suggesting that manufacturers should reimburse the Coast Guard for the estimated \$2,672 in cost per new COA and the \$445 in cost per renewal COA. This alternative will introduce a transfer to cover the Coast Guard's cost of the approvals. Because this alternative will introduce a transfer, there will be no net cost saving from this action. Instead, manufacturing firms will experience an extra \$2,672 in costs each time they apply for a new COA and an extra \$445 in costs each time they try to renew a COA. By raising the costs of approval, the Coast Guard will be increasing entry barriers to manufacturing PFD devices.

Additionally, because our preferred alternative removes the requirements for a COA on nine types of equipment, this alternative will decrease cost savings by both the government cost savings of \$4,735 and the industry cost savings of \$336. Because this alternative will not decrease costs, and increases the entry barrier faced by manufacturing firms, we rejected this alternative.

B. Small Entities

Under the Regulatory Flexibility Act, 5 U.S.C. 601-612, we have considered whether this rule will have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard expects that this rule will not have a significant economic impact on small entities. We expect this rule to result in net cost savings to regulated entities.

We added two years of data to our data analysis in the NPRM; however, the random sample of our dataset is still valid. Using the same number of companies we used in the proposed rule for the final rule, we estimate there to be 11,139 unique vessel operators and 16 equipment manufacturers affected by

this rule. For this analysis, we presumed any company for which we were not able to find Small Business Administration (SBA) size data to be a small entity. An estimated 94 percent of the regulated entities (including the companies without SBA size data) are considered to be small by SBA industry size standards. Using MISLE data, the Coast Guard estimates there to be 11,155 unique companies affected in this rule, of which 10,487 $(0.94 \times 11,155)$ are small. We estimate that the average costs to equipment manufacturers will be reduced by \$1,418 per year, and the average costs to vessel owners and operators will be reduced by \$60 per year as a result of removing Coast Guard approval for the equipment subject to this rulemaking. We found that all small vessel operators and small equipment manufacturers impacted by this rule will have a cost savings less than 1 percent of their annual revenue. No small governmental jurisdictions will be impacted by this rule.

Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

C. Assistance for Small Entities

Under section 213(a) of the Small **Business Regulatory Enforcement** Fairness Act of 1996, Public Law 104-121, we offer to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

D. Collection of Information

This rule calls for a revision to an approved collection of information under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501-3520. As defined in 5 CFR 1320.3(c), "collection of information" comprises reporting, recordkeeping, monitoring, posting, labeling, and other similar actions. The title and description of the information collections, a description of those who must collect the information, and an estimate of the total annual burden follow. The estimate covers the time for reviewing instructions, searching existing sources of data, gathering and maintaining the data needed, and completing and reviewing the collection.

Title: Title 46 CFR Subchapter Q: Lifesaving, Electrical, Engineering and Navigation Equipment, Construction and Materials & Marine Sanitation Devices (33 CFR 159).

OMB Control Number: 1625-0035. Summary of the Collection of Information: The Coast Guard currently collects information from lifesaving equipment manufacturers under 46 CFR chapter I, subchapter Q. The current ICR, 201811-1625-005 (OMB Control Number 1625-0035), accounts for the following collections of information: New Approval Applications, Renewal Approval Applications, Manufacturer Recordkeeping, Servicing Facility Recordkeeping, Servicing Facility Problem Reports, Instruction Materials, Markings, Production Tests and Laboratory Inspections, and **Independent Laboratory Applications** and Recognized Laboratory Applications.

Need for Information: The Coast Guard needs this information to ensure that the manufactured safety equipment meets minimum levels of performance safety and helps prevent death, injuries, and property damage associated with commercial maritime operations.

Proposed Use of Information: The Coast Guard uses the technical plans, drawings, specifications, instruction materials, and markings to determine compliance with the technical regulatory requirements for each piece of equipment. Independent laboratory reports ensure that product and material testing complies with the applicable Coast Guard regulations. Production testing reports ensure that the production stock of the equipment is identical to the stock that was originally tested and approved by the Coast Guard. Independent and recognized laboratory applications ensure that the laboratories have the technical capabilities to conduct the required testing and are independent for the organizations whose products they will test.

Description of the Respondents: The respondents are manufacturers of the safety equipment subject to Coast Guard approval, accepted and recognized independent laboratories that conduct testing of the equipment, and liferaft servicing facilities.

Number of Respondents: The Coast Guard estimates there will be 856

respondents, comprised of 480 equipment manufacturers, 233 liferaft servicing facilities, 139 accepted independent laboratories, and 4 recognized independent laboratories. This rule will impact 16 of these respondents. We do not expect this rule to reduce the total number of respondents, because equipment manufacturers may still manufacture other Coast Guard-approved lifesaving equipment that is not subject to this rule.

Frequency of Response: The number of responses per year will vary by requirement. New application materials, instructions, and markings are required

with the initial COA application, and renewal application materials and markings are required 5 years after the initial application. Production test records and laboratory inspection records are required to be kept annually. The Coast Guard estimates this rule will reduce the number of responses for the following collections of information, presented in table 37, along with the current estimated time to complete each collection.

TABLE 37—TIME BURDEN ESTIMATE BY APPLICATION TYPE

	Hours
New Application	2
Renewal Applications	0.5
Manufacturer Records	0.17
Packing Instruction Materials	0.1
Markings for New Products	0.1
Marking for Revisions	0.1
Testing Records	2
Laboratory Inspection	
Records	24

In table 38, we estimate the reduction in the number of annual responses based on application type.

TABLE 38—Number of Responses Reduced Annually by Application Type

Response type	Previous iteration of ICR Appendix B	Change in burden	Updated ICR Appendix B
New Application Renewal Applications Manufacturer Records Packing Instruction Materials Markings for New Products Marking for Revisions	82	1	81
	544	6	538
	2,715	27	2,688
	272,200	800	271,400
	13,575	5	13,570
	108,600	40	108,560
Testing Records Laboratory Inspection Records	1,828	6	1,820
	1,828	6	1,820

Burden of Response: This rule will not modify the burden of response for any other existing collections of information.

Estimate of Total Annual Burden: The current ICR estimates the total annual burden to be 114,586 hours. As a result of this rule, we estimate the annual burden will be 86,430 hours, for an annual reduction of 28,156 hours. Together, these changes account for a total annual reduction in burden of 27,903 hours. These changes are summarized in table 39.

TABLE 39—SUMMARY OF THE CHANGE IN BURDEN

Baseline total burden	114,586
Program Changes	-27,903
Adjustment Changes	-253
Total Changes	- 28,156
Proposed Total Burden	86,430

This rule is making an adjustment to the current OMB ICR. As required by 44 U.S.C. 3507(d), we will submit a copy of this rule to OMB for its review of the collection of information. You are not required to respond to a collection of information unless it displays a currently valid OMB control number.

E. Federalism

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

It is well settled that States may not regulate in categories reserved for regulation by the Coast Guard. It is also well settled that all of the categories regulated under 46 U.S.C. 2103, 3103, 3306, 3703, 4102, 4502, 7101, and 8101 (design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning of vessels), as well as any other category in which Congress intended the Coast Guard to be the sole source of a vessel's obligations, are within the field foreclosed from regulation by the States. See, e.g., United States v. Locke, 529 U.S. 89 (2000) (finding that the States are foreclosed from regulating tanker vessels), see also Ray v. Atlantic Richfield Co., 435 U.S. 151, 157 (1978)

(State regulation is preempted where "the scheme of federal regulation may be so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it [or where] the Act of Congress may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.' (Citations omitted)) Because this rule involves the design, maintenance, and equipping of vessels; specifically regarding certain survival craft equipment required to be carried in survival craft and rescue boats on certain, specified U.S.-flagged vessels, it relates to vessel standards that are subject to a pervasive scheme of Federal regulation and is therefore foreclosed from regulation by the States. Therefore, because the States may not regulate within these categories, this rule is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

F. Unfunded Mandates

The Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531–1538, requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a

State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Although this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

G. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630 (Governmental Actions and Interference with Constitutionally Protected Property Rights).

H. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988 (Civil Justice Reform) to minimize litigation, eliminate ambiguity, and reduce burden.

I. Protection of Children

We have analyzed this rule under Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks). This rule is not an economically significant rule and will not create an environmental risk to health or risk to safety that might disproportionately affect children.

J. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

K. Energy Effects

We have analyzed this rule under Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use). We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

L. Technical Standards and Incorporation by Reference

The National Technology Transfer and Advancement Act, codified as a note to 15 U.S.C. 272, directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using

these standards will be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule uses the following voluntary consensus standards: ASTM F1003–02, ASTM F1014–02, ISO 18813:2006, ISO 25862:2009, and ISO 17339:2018. The sections that reference these standards and the locations where these standards are available are listed in 46 CFR 160.046–3 and 199.05.

This rule uses technical standards developed by voluntary consensus standards bodies to meet the stringent equipment requirements for survival craft and rescue boats on board U.S.flagged vessels. These standards provide internationally accepted and recognized parameters that equipment must meet in order to ensure its safety, proper usage, and preservation on the seas. The standards being incorporated were developed by either the ASTM or the ISO, which are voluntary consensus standard-setting organizations. The sections that reference these standards and the locations where these standards are available are listed in 46 CFR parts 160 and 199.

Two ASTM standards will be updated and incorporated by reference in this rulemaking: (1) ASTM F1003–02 (Reapproved 2007), "Standard Specification for Searchlights on Motor Lifeboats" (2007); and (2) ASTM F1014–02 (Reapproved 2007), "Standard Specification for Flashlights on Vessels" (2002).

These ASTM standards specify requirements for construction of searchlights and flashlights (respectively), including materials, dimensions, performance, and capability. The newer versions of these standards are not materially different from the previous versions. We are not updating the third ASTM standard already incorporated in § 199.05, ASTM 93–97, "Standard Test Methods for Flash Point by Pensky-Martens Closed Cup Tester."

The following three ISO standards are incorporated by reference in this rulemaking:

1. ISO 18813:2006, Ships and marine technology—Survival equipment for survival craft and rescue boats.

This standard specifies design, performance, and use of various items of survival equipment carried in survival craft and rescue boats complying with SOLAS and the LSA Code. It also

includes guidelines for maintenance and periodic inspections by Administrations or ships' crews for many items.

2. ISO 25862:2009, Ships and marine technology—Marine magnetic compasses, binnacles and azimuth reading devices.

This standard gives requirements regarding construction and performance of marine magnetic compasses for

navigation and steering purposes,

binnacles, and azimuth reading devices. 3. ISO 17339:2018, Ships and marine technology—Life saving and fire protection—Sea anchors for survival

craft and rescue boats.

This standard specifies requirements for the design, performance, and prototype testing of sea anchors fitted to survival craft (liferafts and lifeboats) and rescue boats in accordance with the LSA

Code. With this rulemaking, we also updated our incorporation by reference of International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk (IBC Code), 2016 edition, and the Amendments to the International Code for the Construction and Equipment of Ships Carrying Liquefied Gases in Bulk, (IGC Code), adopted May 22, 2014, to reflect the updated editions. No changes to the specific referenced material have been made between the older editions and the more recent editions. The IBC Code provides an international standard for the safe transport by sea of dangerous and noxious liquid chemicals in bulk. The purpose of the IGC Code is to provide an international standard for the safe transport by sea in bulk of liquefied gases and certain other substances.

The Director of the Federal Register has approved the material in §§ 160.046–3 and 199.05 for incorporation by reference under 5 U.S.C. 552 and 1 CFR part 51. Copies of the material are available from the sources listed in §§ 160.046–3 and 199.05.

Consistent with 1 CFR part 51 incorporation by reference provisions, this material is reasonably available. Interested persons have access to it through their normal course of business, may purchase it from the organization identified in 46 CFR 160.046–3 or 199.05, or may view a copy by means we have identified in those sections.

M. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321-4370f), and have made a determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. A Record of **Environmental Consideration** supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. This rule is categorically excluded under paragraphs L52, L57, and L58 of Appendix A, Table 1 of DHS Instruction Manual 023-01-001-01, Rev. 1. Paragraph L52 pertains to regulations concerning vessel and operation safety standards. Paragraph L57 pertains to regulations concerning manning, documentation, admeasurements, inspection, and equipping of vessels. Paragraph L58 pertains to regulations concerning equipment approval and carriage requirements.

This rule removes the Coast Guard type approval requirement for some survival craft equipment, and replaces it with the requirement that the manufacturer self-certify that their equipment complies with a consensus standard.

List of Subjects

46 CFR Part 121

Communications equipment, Marine safety, Navigation (water), Passenger vessels.

46 CFR Part 160

Incorporation by reference, Marine safety, Reporting and recordkeeping requirements.

46 CFR Part 169

Fire prevention, Incorporation by reference, Marine safety, Reporting and recordkeeping requirements, Schools, Vessels.

46 CFR Part 184

Communications equipment, Marine safety, Navigation (water), Passenger vessels, Reporting and recordkeeping requirements.

46 CFR Part 199

Cargo vessels, Incorporation by reference, Marine safety, Oil and gas exploration, Passenger vessels, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Coast Guard amends 46 CFR parts 121, 160, 169, 184, and 199 as follows:

PART 121—VESSEL CONTROL AND MISCELLANEOUS SYSTEMS AND EQUIPMENT

■ 1. The authority citation for part 121 is revised to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; DHS Delegation 00170.1, Revision No. 01.2

■ 2. Revise § 121.710 to read as follows:

§121.710 First-aid kits.

A vessel must carry either a first-aid kit that meets the requirements in 46 CFR 199.175(b)(10) or a kit with equivalent contents and instructions. For equivalent kits, the contents must be stowed in a suitable, watertight container that is marked "First-Aid Kit". A first-aid kit must be easily visible and readily available to the crew.

PART 160—LIFESAVING EQUIPMENT

■ 3. The authority citation for part 160 is revised to read as follows:

Authority: 46 U.S.C. 2103, 3103, 3306, 3703, 4102, 4302, and 4502; and DHS Delegation 00170.1, Revision No. 01.2, paragraph (II)(92)(b).

■ 4. Amend § 160.010–3 by revising paragraphs (a)(12)(ii) and (e)(7)(ii) to read as follows:

§ 160.010-3 Inflatable buoyant apparatus.

(a) * * *

(12) * * *

(ii) Knives. One knife, of a type designed to minimize the chance of damage to the inflatable buoyant apparatus and secured with a lanyard ready for use near the painter attachment. Any knife may be replaced with a jackknife meeting the requirements in 46 CFR 199.175(b)(16). In addition, an inflatable buoyant apparatus that is permitted to accommodate 13 persons or more must be provided with a second knife that is of the non-folding type;

(e) * * *

(7) * * *

(ii) First-aid kit. A first-aid kit as described in 46 CFR 199.175(b)(10);

Subpart 160.013 [Removed and Reserved]

■ 5. Remove and reserve subpart 160.013, consisting of §§ 160.013-1 through 160.013-5.

Subpart 160.026 [Removed and Reserved]

■ 6. Remove and reserve subpart 160.026, consisting of §§ 160.026–1 through 160.026–7.

Subpart 160.041 [Removed and Reserved]

■ 7. Remove and reserve subpart 160.041, consisting of §§ 160.041–1 through 160.041–6.

Subpart 160.043 [Removed and Reserved]

■ 8. Remove and reserve subpart 160.043, consisting of §§ 160.043-1 through 106.043-6.

Subpart 160.044 [Removed and Reserved]

- 9. Remove and reserve subpart 160.044, consisting of §§ 160.044-1 through 160.044-5.
- 10. Add subpart 160.046, consisting of §§ 160.046–1 through 160.046–11, to read as follows:

Subpart 160.046—Emergency Provisions

Sec.

160.046-1 Scope.

106.046–3 Incorporation by reference.

160.046–5 General requirements for emergency provisions.

160.046–7 Independent laboratory.

160.046–9 Manufacturer certification and labeling.

160.046-11 Manufacturer notification.

§160.046-1 Scope.

This subpart applies to emergency provisions approved to be carried in lifeboats and liferafts, in accordance with 46 CFR 199.175(b)(22).

§ 160.046-3 Incorporation by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the Coast Guard Headquarters. Contact the Coast Guard at: Commandant (CG-ENG-4), U.S. Coast Guard Stop 7509, 2703 Martin Luther King Jr. Avenue SE, Washington, DC 20593-7509; email: typeapproval@ uscg.mil; website: www.dco.uscg.mil/ CG-ENG-4/. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fr.inspection@ nara.gov; website: www.archives.gov/ federal-register/cfr/ibr-locations.html. All approved material is available from the source(s) listed in this section.

- (b) International Organization for Standardization (ISO), Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland; phone: +41 22 749 01 11; email: central@iso.org; web: www.iso.org.
- (1) ISO 18813:2006(E), Ships and marine technology—Survival equipment for survival craft and rescue boats, First edition, April 1, 2006; IBR approved for §§ 160.046-5; 160.046-7; 160.046-11.
 - (2) [Reserved]

§ 160.046-5 General requirements for emergency provisions.

Emergency provisions must meet the requirements found in ISO 18813:2006(E) paragraph 4.31 (incorporated by reference, see § 160.046-3).

§ 160.046-7 Independent laboratory.

Unless the Commandant directs otherwise, an independent laboratory accepted by the Coast Guard under 46 CFR part 159, subpart 159.010, must perform or witness, as appropriate, inspections, tests, and oversight required by ISO 18813:2006(E) paragraph 4.31 (incorporated by reference, see § 160.046-3). Approval and production tests of emergency provisions must be carried out in accordance with the procedures for independent laboratory inspections in 46 CFR part 159, subpart 159,007, and in this section unless the Commandant authorizes alternative tests and inspections. The Commandant may prescribe additional production tests and inspections necessary to maintain quality control and to monitor compliance with the requirements of this subpart.

§ 160.046-9 Manufacturer certification and

- (a) Each provision must be certified by the manufacturer as complying with the requirements of this subpart.
- (b) The container should be clearly and permanently marked with:
- (1) The name and address of the approval holder;
- (2) The U.S. Coast Guard Approval number:
- (3) The total food energy value of provisions in the container in calories and kiloJoules;
 - (4) The lot number;
- (5) The month and year the provision was packed; and
- (6) The month and year of expiration (5 years after the date of packing).
- (c) The emergency provision must include waterproof instructions for use, assuming consumption of 3350 kiloJoules per person per day.

§ 160.046-11 Manufacturer notification.

- (a) Each manufacturer of emergency provisions approved in accordance with the specifications of this subpart must send a test report required by ISO 18813:2006(E) paragraph 4.31.2 (incorporated by reference, see § 160.046-3) to the Commandant (CG-ENG-4), U.S. Coast Guard Stop 7509, 2703 Martin Luther King Jr. Avenue SE, Washington, DC 20593-7509 or email typeapproval@uscg.mil:
 - (1) With the application for approval;
- (2) Every year as long as the manufacturer continues to produce provisions: and
- (3) Each time the contents of the emergency provisions change.
 - (b) [Reserved]
- 11. Amend § 160.051–11 by revising paragraph (b) to read as follows:

§ 160.051-11 Equipment required for Coastal Service inflatable liferafts.

(b) Knife. One knife, of a type designed to minimize the chance of damage to the inflatable liferaft and secured with a lanyard. In addition, an inflatable liferaft that is permitted to accommodate 13 persons or more must be provided with a second knife that is of the non-folding type. Any knife may be replaced with a jackknife meeting the requirements in 46 CFR 199.175(b)(16).

Subpart 160.054 [Removed and Reserved1

■ 12. Remove and reserve subpart 160.054, consisting of §§ 160.054–1 through 106.054-7.

Subpart 160.061 [Removed and Reserved]

- 13. Remove and reserve subpart 160.061, consisting of §§ 160.061–1 through 106.061-5.
- 14. Amend § 160.135–7 by revising paragraph (b)(23) to read as follows:

§ 160.135-7 Design, construction, and performance of lifeboats.

*

(b) * * *

(23) Bilge pump. Each lifeboat that is not automatically self-bailing must be fitted with a manual bilge pump that meets the requirements in 46 CFR 199.175(b)(2). Each such lifeboat with a capacity of 100 persons or more must carry an additional manual bilge pump or an engine-powered bilge pump.

■ 15. Amend § 160.151–21 by revising paragraphs (b), (h), (o), and (q) through (s) as follows:

§ 160.151-21 Equipment required for SOLAS A and SOLAS B inflatable liferafts.

(b) Jackknife (IMO LSA Code, as amended by Resolution MSC.293(87), Chapter IV/4.1.5.1.2). Each folding knife must be a jackknife meeting the requirements in 46 CFR 199.175(b)(16).

(h) First-aid kit (IMO LSA Code, as amended by Resolution MSC.293(87), Chapter IV/4.1.5.1.8). Each first-aid kit must meet the requirements in 46 CFR 199.175(b)(10).

(o) Signalling mirror (IMO LSA Code, as amended by Resolution MSC.293(87), Chapter IV/4.1.5.1.15). Each signalling mirror must meet the requirements in 46 CFR 199.175(b)(19).

(q) Fishing tackle (IMO LSA Code, as amended by Resolution MSC.293(87), Chapter IV/4.1.5.1.17). The fishing tackle must meet the requirements in 46 CFR 199.175(b)(11).

(r) Food rations (IMO LSA Code, as amended by Resolution MSC.293(87), *Chapter IV/4.1.5.1.18).* The food rations must meet the requirements in 46 CFR 199.175(b)(22).

(s) Drinking water (IMO LSA Code, as amended by Resolution MSC.293(87), Chapter IV/4.1.5.1.19). Emergency drinking water must meet the requirements in 46 CFR 199.175(b)(40). The desalting apparatus or reverse osmosis desalinator must be approved by the Commandant under approval series 160.058.

■ 16. Amend § 160.156–7 by revising paragraph (b)(22) to read as follows:

§ 160.156-7 Design, construction and performance of rescue boats and fast rescue boats.

(b) * * *

(22) Manual bilge pump. Each rescue boat that is not automatically selfbailing must be fitted with a manual bilge pump that meets the requirements in 46 CFR 199.175(b)(2), or an enginepowered bilge pump.

PART 169—SAILING SCHOOL VESSELS

■ 17. The authority citation for part 169 is revised to read as follows:

Authority: 33 U.S.C. 1321(j); 46 U.S.C. 3306, 6101; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp., p. 793; DHS Delegation 00170.1, Revision No. 01.2; § 169.117 also issued under the authority of 44 U.S.C. 3507.

■ 18. Amend § 169.115 by revising paragraphs (a) and (e) to read as follows:

§ 169.115 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the Coast Guard Headquarters and at the National Archives and Records Administration (NARA). Contact the Coast Guard at: Commandant (CG-ENG-4), U.S. Coast Guard Stop 7509, 2703 Martin Luther King Jr. Avenue SE, Washington, DC 20593-7509; email: tvpeapproval@uscg.mil; website: www.dco.uscg.mil/CG-ENG-4/. For information on the availability of this material at NARA, email: fr.inspection@ nara.gov; website: www.archives.gov/ federal-register/cfr/ibr-locations.html. The material may be obtained from the source(s) in the following paragraph(s) of this section.

* * * * *

- (e) The Textile Color Card Association of the United States, Inc. 200 Madison Avenue, New York. (For availability of this material, contact the Coast Guard—see paragraph (a) of this section.)
- (1) Cable No. 70072, Standard Color Card of America, Ninth edition, 1941 for § 169.529(b).
 - (2) [Reserved]

* * * * *

■ 19. Revise § 169.527 to read as follows:

§ 169.527 Required equipment for lifeboats.

- (a) All lifeboats must be equipped in accordance with table 1 to 46 CFR 199.175 except as provided in paragraphs (b) and (c) of this section.
- (b) The following equipment must be carried in addition to the equipment required under 46 CFR 199.175:
 - (1) Cover;
 - (2) Ditty bag; and
 - (3) Mast and sail.
- (c) If operating on protected waters, lifeboat equipment need only to consist of the following:
 - (1) Boathook—(1);
 - (2) Bucket—(1);
- (3) Fire extinguisher—(2) U.S. Coast Guard-approved Type B:C (motor propelled lifeboats only);
 - (4) Hatch—(1);
 - (5) Lifeline—(1);
 - (6) Oar unit—(1);
 - (7) Painter—(1);
 - (8) Plug—(1);
 - (9) Oarlock unit—(1); and
- (10) Toolkit (motor propelled lifeboats only).
- \blacksquare 20. Revise § 169.529 to read as follows:

§ 169.529 Description of lifeboat equipment.

(a) All lifeboat equipment must meet the requirements under 46 CFR 199.175,

- except as provided in paragraph (b) of this section.
- (b) The following equipment, carried in addition to the equipment required under 46 CFR 199.175, must meet the following requirements:
- (1) Cover, protecting. The cover must be of highly visible color and capable of protecting the occupants against exposure. A cover is not required for fully enclosed lifeboats.
- (2) Ditty bag. The ditty bag must consist of a canvas bag or equivalent and must contain a sailmaker's palm, needles, sail twine, marline, and marlin spike, except that motor-propelled lifeboats need not carry a ditty bag.
- (3) Mast and sail. A unit, consisting of a standing lug sail together with the necessary spars and rigging, must be provided in accordance with table 1 to this section, except that motor-propelled lifeboats need not carry a mast or sails. The sails must be of good quality canvas, or other material acceptable to the Commandant, colored Indian Orange (Cable No. 70072, Standard Color Card of America; incorporated by reference, see § 169.115). Rigging must consist of galvanized wire rope not less than 3/16-inch in diameter. The mast and sail must be protected by a suitable cover.

TABLE 1 TO § 169.529

ngth of	Length of lifeboat, feet					Standing	lug sail							Mast 1			Yard1	
		0,00	Luff an	Luff and head	Leach length	ength	Foot length	ength	Clew to throat	throat	3000	Commercial designation	Len	-ength	Diamotor	Length	gth) iomotor
Over—	Not over—	square feet	Feet	Inches	Feet	Inches	Feet	Inches	Feet	Inches	square yard	number	Feet	Inches	inches	Feet	Inches	inches
	17	28	5	=	12	-	8	10	10	10	14.35	10	1	N	8	9	1	2
17	19	74	9	80	13	80	9	0	12	7	14.35	10	12	9	က	7	00	2
19	21	93	7	2	15	-	Ξ	2	13	80	14.35	10	13	10	31/2	80	2	21/2
21	23	113	80	ო	16	=	12	4	15	-	14.35	10	15	2	31/2	0	က	21/2
23	25	135	6	0	48	9	13	9	16	9	14.35	10	16	9	4	9	0	က
25	27	158	6	თ	20	0	14	7	17	9	17.50	80	17	10	4	9	6	က
27	29	181	9	ß	2	2	15	7	19	-	17.50	80	19	2	41/2	=	2	31/4
29	31	203	Ξ	0	22	∞	16	9	20	က	20.74	9	20	9	41/2	12	0	31/4
312																		
1 Mast It 2 Subjec	¹ Mast lengths measured from he ² Subject to special consideration.	$^{\rm I}$ Mast lengths measured from heel to center of upper halyard sheave. Mast $^{\rm 2}$ Subject to special consideration.	center of	upper hal	yard shea		liameters	measured	at thwart.	Mast and	diameters measured at thwart. Mast and yard shall be of clear-grained spruce, fir, or equivalent.	of clear-grainec	d spruce, fi	ir, or equiv	alent.			

PART 184—VESSEL CONTROL AND MISCELLANEOUS SYSTEMS AND **EQUIPMENT**

■ 21. The authority citation for part 184 is revised to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; DHS Delegation 00170.1, Revision No. 01.2.

■ 22. Revise § 184.710 to read as follows:

§ 184.710 First-aid kits.

A vessel must carry either a first-aid kit that meets the requirements in 46 CFR 199.175(b)(10) or a kit with equivalent contents and instructions. For equivalent kits, the contents must be stowed in a suitable, watertight container that is marked "First-Aid Kit". A first-aid kit must be easily visible and readily available to the crew.

PART 199—LIFESAVING SYSTEMS FOR CERTAIN INSPECTED VESSELS

■ 23. The authority citation for part 199 is revised to read as follows:

Authority: 46 U.S.C. 2103, 3103, 3306, and 3703; and DHS Delegation 00170.1, Revision No. 01.2, paragraph (II)(92)(b).

■ 24. Revise § 199.05 to read as follows:

§ 199.05 Incorporation by reference.

Certain material is incorporated by reference in this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the Coast Guard Headquarters and at the National Archives and Records Administration (NARA). Contact the Coast Guard at: Commandant (CG-ENG-4), U.S. Coast Guard Stop 7509, 2703 Martin Luther King Jr. Avenue SE, Washington, DC 20593-7509, email typeapproval@uscg.mil or visit https:// www.dco.uscg.mil/CG-ENG-4/. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: fr.inspection@nara.gov or go to www.archives.gov/federal-register/cfr/ *ibr-locations.html.* The material may be obtained from the following source(s):

- (a) ASTM International (ASTM). 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959; phone: (610) 832 9500; email service@astm.org; web: www.astm.org.
- (1) ASTM D 93-97, Standard Test Methods for Flash-Point by Pensky-Martens Closed Cup Tester, approved July 10, 1997; IBR approved for §§ 199.261; 199.290.

- (2) ASTM F1003-02 (Reapproved 2007), Standard Specification for Searchlights on Motor Lifeboats, approved May 1, 2007; IBR approved for § 199.175.
- (3) ASTM F1014-02 (Reapproved 2007), Standard Specification for Flashlights on Vessels, approved May 1, 2007; IBR approved for § 199.175.
- (b) International Maritime Organization (IMO). Publications Section, 4 Albert Embankment, London, SE1 7SR, United Kingdom; phone: +44 (0)20 7735 7611; email: info@imo.org; web: www.imo.org.
- (1) IBC Code, International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk, 2016 edition, copyright 2016, Chapter 2 Ship survival capability and location of cargo tanks; IBR approved for § 199.280.
- (2) IBC Code, International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk, 2016 edition, copyright 2016, Chapter 17 Summary of minimum requirements; IBR approved for § 199.30.
- (3) MSC Circular 699, Revised Guidelines for Passenger Safety Instructions, issued July 17, 1995, IBR approved for § 199.217.
- (4) Resolution A.520(13), Code of Practice for the Evaluation, Testing and Acceptance of Prototype Novel Lifesaving Appliances and Arrangements. adopted November 17, 1983; IBR approved for § 199.40.
- (5) Resolution A.657(16), Instructions for Action in Survival Craft, adopted October 19, 1989; IBR approved for § 199.175.
- (6) Resolution A.658(16), Use and Fitting of Retro-reflective Materials on Life-saving Appliances, adopted October 19, 1989; IBR approved for §§ 199.70; 199.176.
- (7) Resolution A.760(18), Symbols Related to Life-saving Appliances and Arrangements, adopted November 4, 1993, IBR approved for §§ 199.70;
- (8) Resolution MSC.370(93), Amendments to the International Code for the Construction and Equipment of Ships Carrying Liquefied Gases in Bulk, (IGC Code), adopted May 22, 2014; IBR approved for §§ 199.30; 199.280.
- (c) International Standard Organization (ISO). Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland; phone: +41 22 749 01 11; email: central@iso.org; web: www.iso.org.
- (1) ISO 17339:2018(E), Ships and marine technology—Life saving and fire protection—Sea anchors for survival

craft and rescue boats, Second edition, July 2018; IBR approved for § 199.175.

- (2) ISO 18813:2006(E), Ships and marine technology—Survival equipment for survival craft and rescue boats, First edition, April 1, 2006; IBR approved for
- (3) ISO 25862:2009(E), Ships and marine technology—Marine magnetic compasses, binnacles and azimuth reading devices, First edition, May 15, 2009; IBR approved for § 199.175.

§ 199.30 [Amended]

- 25. Amend § 199.30 in the definition
- for "Toxic vapor or gas" as follows:

 a. Remove the text "IBC Code" and add, in its place, the text "IBC Code; incorporated by reference, see § 199.05";
- b. Remove the text "IGC Code" and add, in its place, the text "IGC Code; incorporated by reference, see § 199.05".
- 26. Amend § 199.175 as follows:
- a. In paragraph (a)(4), remove the word "and";
- \blacksquare b. Redesignate paragraph (a)(5) as paragraph (a)(6);
- \blacksquare c. Add new paragraph (a)(5);
- d. In the introductory text to paragraph (b), remove the text "table 199.175 of this section" and add, in its place, the text "table 1 to this section";
- e. Revise the introductory text to paragraph (b)(2), paragraphs (b)(5), (6), (9) through (13), (16), (17), and (19), and (b)(27)(i):
- f. In paragraph (b)(28)(i), remove the text "F 1003" and add, in its place, the text "F1003";
- g. Revise paragraph (b)(40) introductory text;
- h. Redesignate paragraphs (b)(40)(i) and (ii) as paragraphs (b)(40)(iii) and
- i. Add new paragraphs (b)(40)(i) and (ii);
- j. In newly-redesignated paragraph (b)(40)(iv), remove the words "reverse osmosis" and add, in their place, the text "reverse-osmosis"
- k. Add paragraph (c) immediately before table 199.175;
- l. Designate table 199.175 as table 1 to § 199.175;
- m. In newly-designated table 1 to § 199.175, revise entries 5 and 17; and
- n. Add footnote 11 to the footnotes following table 1 to § 199.175.

The revisions and additions read as follows:

§ 199.175 Survival craft and rescue boat equipment.

(a) * * *

(5) Must be marked with either the Coast Guard approval number or the standard that the product meets, as applicable; and

- (b) * * *
- (2) Bilge pump. The bilge pump must meet the requirements in ISO 18813:2006(E) paragraph 4.3 (incorporated by reference, see § 199.05) and must be installed in a ready-to-use condition.

(5) Can opener. A can opener must meet the requirements in ISO 18813:2006(E) paragraph 4.43 (incorporated by reference, see § 199.05). A can opener may be in a jackknife meeting the requirements in

*

paragraph (b)(16) of this section. (6) *Compass.* The compass and its

mounting arrangement must meet the requirements in ISO 18813:2006(E) paragraph 4.6 (incorporated by

reference, see § 199.05).

(i) In a totally enclosed lifeboat, the compass must be permanently fitted at the steering position; in any other boat it must be provided with a binnacle, if necessary, to protect it from the weather, and with suitable mounting arrangements.

(ii) The compass must be tested in accordance with the provisions in ISO 25862:2009(E) Annex H (incorporated by reference, see § 199.05) by an independent laboratory accepted by the Coast Guard in accordance with part 159, subpart 159.010, of this chapter.

(9) Fire extinguisher. The fire extinguisher must be approved under approval series 162.028. The fire extinguisher must have a rating of a 40–B:C. Two 10–B:C extinguishers may be carried in place of a 40–B:C extinguisher. Extinguishers with larger numerical ratings or multiple letter designations may be used instead.

(10) First-aid kit. Each first-aid kit must meet the requirements in ISO 18813:2006(E) paragraph 4.12 (incorporated by reference, see

§ 199.05).

(i) A first-aid kit may be considered acceptable if it meets all of the requirements of ISO 18813:2006(E) paragraph 4.12, except that it does not contain the burn preparations. It must be clearly marked on the first-aid kit

that it does not include the burn preparations.

- (ii) The active ingredients in medicinal products must conform to over-the-counter (OTC) drug regulations set out in 21 CFR part 330.
- (11) Fishing kit. The fishing kit must meet the requirements in ISO 18813:2006(E) paragraph 4.13 (incorporated by reference, see § 199.05).
- (12) Flashlight. The flashlight must be a type I or type III that is constructed and marked in accordance with ASTM F1014 (incorporated by reference, see § 199.05). One spare set of batteries and one spare bulb, stored in a watertight container, must be provided for each flashlight.
- (13) *Hatchet*. The hatchet must be suitable for cutting a rope towline or painter in an emergency and must not require assembly or unfolding.
- (i) The hatchet must be at least 14 inches in length and have a cutting edge of approximately 3½ inches in length, with a hardened steel or equivalent alloy head.
- (ii) The hatchet must be provided a lanyard at least 3 feet in length.
- (iii) The hatchet must be stowed in brackets near the release mechanism and, if more than one hatchet is carried, the hatchets must be stowed at opposite ends of the boat.

* * * * *

- (16) Jackknife. The jackknife must consist of a one-bladed knife fitted with a can opener and attached to the boat by its lanyard. The jackknife must meet the requirements in ISO 18813:2006(E) paragraph 4.19 (incorporated by reference, see § 199.05).
- (17) *Knife.* The knife must be of the non-folding type with a buoyant handle as follows:
- (i) The knife for a rigid liferaft must be secured to the raft by a lanyard and stowed in a pocket on the exterior of the canopy near the point where the painter is attached to the liferaft. If an approved jackknife is substituted for the second knife required on a liferaft equipped for 13 or more persons, the jackknife must

- also be secured to the liferaft by a lanvard.
- (ii) The knife in an inflatable or rigidinflatable rescue boat must be of a type designed to minimize the possibility of damage to the fabric portions of the hull.
- (iii) Any knife may be replaced with a jackknife meeting the requirements in paragraph (b)(16) of this section.
- (19) *Mirror*. The signalling mirror must meet the requirements in ISO 18813:2006(E) paragraph 4.23 (incorporated by reference, see § 199.05).

(27) * * *

- (i) The sea anchor for a lifeboat, rescue boat, and rigid liferaft must meet the requirements in ISO 17339:2018(E) (incorporated by reference, see § 199.05).
- (40) *Water*. The water must meet the requirements in ISO 18813:2006(E) paragraph 4.46 (incorporated by reference, see § 199.05).
- (i) The water must meet the U.S. Public Health Service "Drinking Water Standards" in 40 CFR part 141 to suitably protect the container against corrosion. After treatment and packing, the water must be free from organic matter, sediment, and odor. It must have a pH between 7.0 and 9.0 as determined by means of a standard pH meter using glass electrodes. Water quality must be verified by the local municipality or independent laboratory accepted by the Coast Guard in accordance with part 159, subpart 159.010, of this chapter.
- (ii) Containers of emergency drinking water must be tested in accordance with the provisions in ISO 18813:2006(E) by an independent laboratory accepted by the Coast Guard in accordance with part 159, subpart 159.010, of this chapter.
- (c) Any Coast Guard-approved equipment on board before December 14, 2022 may remain on board as long as it remains in good and serviceable condition.

TABLE 1 TO § 199.175—SURVIVAL CRAFT EQUIPMENT

		I	International voyage		Short international voyage		
Item No.	Item	Lifeboat	Rigid liferaft (SOLAS A pack)	Rescue boat	Lifeboat	Rigid liferaft (SOLAS B pack)	Rescue boat
*	*	*	*	*		*	*
5	Can opener 11	3	3		3		

TABLE 1 TO § 199.175—SURVIVAL CRAFT EQUIPMENT—Continued

		lı	nternational voyage	е	Short	t international vo	yage	
Item No.	Item	Lifeboat	Rigid liferaft (SOLAS A pack)	Rescue boat	Lifeboat	Rigid liferaft (SOLAS B pack)	Rescue t	ooat
*	*	*	*	*		*	*	
17	Knife 1 4 11	1	1	1	1	1		1
*	*	*	*	*		*	*	

Notes:

- ¹ Each liferaft equipped for 13 persons or more must carry two of these items.
- ⁴ A hatchet counts towards this requirement in rigid rescue boats.

§199.280 [Amended]

■ 27. Amend § 199.280 in paragraphs (e)(2) and (3) by removing the words "in

Bulk" and adding, in their place, the text "in Bulk (incorporated by reference, see § 199.05)".

Dated: October 26, 2022.

W.R. Arguin,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Prevention Policy. [FR Doc. 2022–23666 Filed 11–10–22; 8:45 am]

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¹¹ One (1) jackknife may replace one (1) can opener and one (1) knife.



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Part IV

Department of Defense General Services Administration National Aeronautics and Space Administration

48 CFR Parts 1, 4, 9, et al.

Federal Acquisition Regulation: Disclosure of Greenhouse Gas Emissions and Climate-Related Financial Risk; Proposed Rule

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1, 4, 9, 23 and 52

[FAR Case 2021-015, Docket No. FAR-2021-0015, Sequence No. 1]

RIN 9000-AO32

Federal Acquisition Regulation: Disclosure of Greenhouse Gas Emissions and Climate-Related Financial Risk

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to implement a requirement to ensure certain Federal contractors disclose their greenhouse gas emissions and climate-related financial risk and set science-based targets to reduce their greenhouse gas emissions.

DATES: Interested parties should submit written comments to the Regulatory Secretariat Division at the address shown below on or before January 13, 2023 to be considered in the formation of the final rule.

ADDRESSES: Submit comments in response to FAR Case 2021–015 to the Federal eRulemaking portal at https://www.regulations.gov by searching for "FAR Case 2021–015". Select the link "Comment Now" that corresponds with "FAR Case 2021–015". Follow the instructions provided on the "Comment Now" screen. Please include your name, company name (if any), and "FAR Case 2021–015" on your attached document. If your comment cannot be submitted using https://www.regulations.gov, call or email the points of contact in the FOR FURTHER INFORMATION CONTACT section of this document for alternate instructions.

Instructions: Please submit comments only and cite "FAR Case 2021–015" in all correspondence related to this case. Comments received generally will be posted without change to https://www.regulations.gov, including any personal and/or business confidential information provided. Public comments may be submitted as an individual, as an organization, or anonymously (see frequently asked questions at https://www.regulations.gov/faq). To confirm receipt of your comment(s), please

check https://www.regulations.gov, approximately two to three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact Ms. Jennifer Hawes, Procurement Analyst, at 202–255–9194 or by email at *jennifer.hawes@gsa.gov*. For information pertaining to status, publication schedules, or alternate instructions for submitting comments if https://www.regulations.gov cannot be used, contact the Regulatory Secretariat Division at 202–501–4755 or GSARegSec@gsa.gov. Please cite FAR Case 2021–015.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA are proposing to revise the FAR to implement section 5(b)(i) of Executive Order (E.O.) 14030, Climate-Related Financial Risk, to require major Federal suppliers to publicly disclose greenhouse gas (GHG) emissions and climate-related financial risk and to set science-based reduction targets. As stated in the Fourth National Climate Assessment (https:// nca2018.globalchange.gov/) and the Intergovernmental Panel on Climate Change (IPCC) Sixth Assessment Report (https://www.ipcc.ch/report/ar6/wg2/), the intensifying impacts of climate change present physical risks, such as increased extreme weather risk leading to supply chain disruptions, and increasing risks to infrastructure, investments, and businesses. The global, rapid shift away from carbon-intensive energy sources and industrial processes towards decarbonized, climate-resilient economies will help to mitigate these risks while also enhancing U.S. competitiveness and economic growth, promoting environmental justice, and creating well-paying job opportunities for American workers. Yet, these risks and opportunities can remain hidden.

The foundation to properly analyze and mitigate climate risks is public and standardized disclosure, which will enable the Federal Government to conduct prudent fiscal management of all major Federal suppliers. To that end, section 5(b)(i) of the E.O. directs the Federal Acquisition Regulatory Council (FAR Council), in coordination with the Council on Environmental Quality (CEQ) and the heads of relevant agencies, to consider an amendment to the FAR to ensure that major Federal suppliers disclose their GHG emissions and climate-related financial risk and set science-based targets to reduce their GHG emissions. The purpose of this proposed rule is to amend the FAR to establish a policy to ensure major

Federal suppliers make the required disclosures and set targets to reduce their GHG emissions.

On December 8, 2021, the Office of Management and Budget (OMB) issued memorandum M-22-06 pursuant to section 510(a) of E.O. 14057, Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability. Section II.1. of the OMB memo states that the FAR Council should leverage existing third-party standards and systems, including the Task Force on Climaterelated Financial Disclosures (TCFD) Recommendations, the CDP (formerly Carbon Disclosure Project) reporting system, and Science Based Targets Initiative (SBTi) criteria, or equivalents, in the development of regulatory amendments to promote contractor attention regarding reduced carbon emissions and Federal sustainability.

On March 21, 2022, in response to the growth in investor demand for and company disclosure of information about climate change risks, impacts, and opportunities, the Securities and Exchange Commission (SEC) published on its website at https://www.sec.gov/ rules/proposed.shtml a proposed rule to facilitate the disclosure of consistent, comparable, and reliable information on climate-related financial risk. The proposed rule, entitled "The Enhancement and Standardization of Climate-Related Disclosures for Investors," was subsequently published in the Federal Register on April 11, 2022 (see 87 FR 21334). The SEC is proposing to require SEC registrants, including publicly listed/traded companies, to disclose in their registration statements and annual reports their climate-related financial risk and related metrics, including GHG emissions metrics. Parts of the SEC proposed rule leverage existing standards, such as the GHG Protocol Corporate Accounting and Reporting Standard and the recommendations of the TCFD, the same standards that are leveraged in this proposed rule (see section II.A. of this preamble). While the SEC proposed rule did not include a requirement for SEC registrants to set science-based targets, it did propose that SEC registrants disclose targets if they have adopted one. While there are some similarities between the content of the disclosures in the SEC and FAR proposed rules, this proposed FAR rule specifically requires the Federal contractors with significant Federal contracts to provide their disclosures using the CDP Climate Change Questionnaire to maximize the consistency, comparability, and accessibility of disclosure data for use in managing Federal procurements and

supply chains. In addition, per this proposed FAR rule, major contractors will also be required to set science-based targets to reduce their GHG emissions.

II. Discussion and Analysis

To implement the new disclosure and target requirements of E.O. 14030, DoD, GSA, and NASA are proposing to create a new FAR subpart at 23.XX, entitled "Public Disclosure of Climate Information," to expand the climaterelated representations in the solicitation provisions at FAR 52.223-22, Public Disclosure of Climate Information—Representation, and 52.212-3, Offeror Representations and Certifications—Commercial Products and Commercial Services, and to establish a new standard of responsibility for certain contractors in FAR subpart 9.1. The following is a discussion and analysis of the proposed FAR amendments:

A. Significant and Major Contractors

Section 5(b)(i) of E.O. 14030 directs the FAR Council to consider an amendment to the FAR to ensure major Federal suppliers disclose their GHG emissions and climate-related financial risk and set science-based targets to reduce their GHG emissions. This rule proposes to separate "major Federal suppliers" into two categories: significant contractors and major contractors. Per this proposed rule, both significant contractors and major contractors would be subject to annual Scope 1 and Scope 2 GHG emissions disclosure requirements (discussed in section II.B.1. of this preamble), while only major contractors would be subject to the annual climate disclosure, which includes disclosure of Scope 3 GHG emissions, and science-based target requirements (discussed in section II.B.2. and II.B.3. of this preamble).

For the purposes of this rule, an offeror is considered a "significant contractor" if the offeror received \$7.5 million or more, but not exceeding \$50 million, in Federal contract obligations (as defined in OMB Circular A-11) in the prior Federal fiscal year as indicated in the System for Award Management (SAM) at https://www.sam.gov. An offeror is considered a "major contractor" if the offeror received more than \$50 million in Federal contract obligations (as defined in OMB Circular A-11) in the prior Federal fiscal year as indicated in SAM. According to award data available in the Federal Procurement Data System (FPDS), there were approximately 4,413 entities that received between \$7.5 million and \$50 million in Federal contract obligations

in FY 2021, of which 2,835 (64 percent) are estimated to be small businesses. There were approximately 1,353 entities that received more than \$50 million in Federal contract obligations in FY 2021, of which 389 (29 percent) are estimated to be small businesses.

This distinction between major contractors and significant contractors is important to ensure this rule collectively applies the requirements to entities receiving the most annual Federal contract obligations, to obtain the most responsibility for the management of GHG emissions and climate risks impacting the Federal Government's supply chains. The major contractor requirements would address 64 percent of Federal Government spend and approximately 69 percent of supply chain GHG impacts, of which 31 percent of major contractors already report disclosing their GHG emissions through SAM. Significant contractors receive fewer contract obligations, with only 10 percent disclosing their GHG emissions through SAM. Therefore, the reporting burden is significantly lessened for these companies by only reporting Scope 1 and 2 emissions. Collectively, this rule will cover 86 percent of annual spend and about 86 percent of supply chain GHG impacts. It will also provide a better understanding of the Federal supply chain impacts, including Scope 3 emissions reported by major contractors.

B. Policy.

As provided in paragraph (a) of the new section at FAR 23.XX03, a contracting officer is required to treat a significant or major contractor as nonresponsible, unless it has (itself or through its immediate owner or highestlevel owner) inventoried its annual GHG emissions, and the significant or major contractor has disclosed its total annual emissions in SAM. Per paragraph (b) of FAR section 23.XX03, a major contractor shall also be treated as nonresponsible, unless it has (itself or through its immediate owner or highestlevel owner) made available on a publicly accessible website an annual climate disclosure that was completed using the CDP Climate Change Questionnaire in its current or previous fiscal year and set targets to reduce its emissions.

The following is a discussion of the specific compliance requirements, which are subject to the exceptions and starting dates described in sections II.C. and II.E. of this preamble. A discussion of the various standards specified for compliance is provided in section II.D. of this preamble.

1. GHG Inventory

A significant or major contractor (itself or through its immediate owner or highest-level owner) is required to have completed within its current or previous fiscal year a GHG inventory of its annual Scope 1 and Scope 2 emissions. The significant or major contractor must also disclose in SAM at https://www.sam.gov the total annual Scope 1 and Scope 2 emissions identified through its most recent GHG inventory. Per OMB Memo M-22-06 (and as currently defined at FAR 23.001), greenhouse gases include carbon dioxide, methane, nitrous oxide, hydrofluorocarbons, perfluorocarbons, nitrogen trifluoride, and sulfur hexafluoride. Scope 1 emissions include GHG emissions from sources that are owned or controlled by the reporting company. Scope 2 emissions include GHG emissions associated with the generation of electricity, heating and cooling, or steam, when these are purchased or acquired for the reporting company's own consumption but occur at sources owned or controlled by another entity. In conducting a GHG inventory, the significant or major contractor (or their immediate or highest-level owner) must follow the **GHG** Protocol Corporate Accounting and Reporting Standard (see section II.D.1. of this preamble) to develop a quantified list of the Scope 1 and Scope 2 GHG emissions. Companies may calculate emissions using the calculation tool of their choice, as long as it is in alignment with the GHG Protocol Corporate Accounting and Reporting Standard. The Environmental Protection Agency (EPA) offers one such tool: a simplified GHG emissions calculator (see https://www.epa.gov/ climateleadership/simplified-ghgemissions-calculator). The inventory must represent emissions during a continuous period of 12 months, ending not more than 12 months before the inventory is completed.

Major contractors are also required to conduct a GHG inventory of their relevant Scope 3 emissions, as discussed in the next section of this preamble. The requirement to inventory Scope 3 emissions is not applicable to significant contractors.

2. Annual Climate Disclosure

A major contractor (itself or through its immediate owner or highest-level owner) is required to complete an annual climate disclosure within its current or previous fiscal year. The annual climate disclosure is a set of disclosures by an entity that aligns with recommendations of the TCFD (see section II.D.2. of this preamble). The

disclosure includes a GHG inventory of not only the Scope 1 and Scope 2 emissions, but also relevant Scope 3 emissions, which are emissions that are a consequence of the operations of the reporting entity but occur at sources other than those owned or controlled by the entity. The annual climate disclosure also describes the entity's climate risk assessment process and any risks identified. For the purposes of this rule, a major contractor submits its annual climate disclosure by completing those portions of the CDP Climate Change Questionnaire that align with the TCFD as identified by CDP (https:// www.cdp.net/en/guidance/how-cdp-isaligned-to-the-tcfd) (see section II.D.3. of this preamble) within its current or previous fiscal year. The annual climate disclosure must be made available on a publicly accessible website, which could be the company's own website or the CDP website.

3. Science-Based Targets

The major contractor (itself or through its immediate owner or highest-level owner) is also required to develop science-based targets and have the targets validated by SBTi (see section II.D.4. of this preamble). A sciencebased target is a target for reducing GHG emissions that is in line with reductions that the latest climate science deems necessary to meet the goals of the Paris Agreement to limit global warming to well below 2 °C above pre-industrial levels and pursue efforts to limit warming to 1.5 °C (see SBTi frequently asked questions at https://sciencebased targets.org/faqs#what-are-sciencebased-targets). For information on the latest climate science see 2018 Intergovernmental Panel on Climate Change (IPCC) Special Report on 1.5 °C at https://www.ipcc.ch/sr15/. These targets must be validated by SBTi within the previous five calendar years and must also be made available on a publicly accessible website. Validated targets published by SBTi on the SBTi website satisfy this requirement.

4. Means of Compliance

The proposed rule allows for a significant or major contractor to be considered in compliance with the new policy at 23.XX03 if the action was completed by the significant or major contractor itself or through its immediate or highest-level owner, except that the significant or major contractor itself must report the results of the GHG inventory in SAM (see 23.XX03(a)(2)).

The definitions of "immediate owner" and "highest-level owner" currently included in the provisions at FAR

52.204-17, Ownership or Control of Offeror, and the commercial provision at FAR 52.212-3 are adopted for this rule. Specifically, an "immediate owner" is an entity, other than the offeror, that has direct control of the offeror. Indicators of control include, but are not limited to, one or more of the following: ownership or interlocking management, identity of interests among family members, shared facilities and equipment, and the common use of employees. "Highest-level owner" means the entity that owns or controls an immediate owner of the offeror, or that owns or controls one or more entities that control an immediate owner of the offeror. No entity owns or exercises control of the highest-level

C. Exceptions

A new FAR section at 23.XX04 outlines certain exceptions. Per FAR 23.XX04(a), a significant or major contractor is not required to inventory its Scope 1 or Scope 2 emissions and a major contractor is not required to complete an annual climate disclosure or set science-based targets, as described in section II.B. of this preamble, if it is—

- An Alaska Native Corporation, a Community Development Corporation, an Indian tribe, a Native Hawaiian Organization, or a Tribally owned concern, as those terms are defined at 13 CFR 124.3;
- A higher education institution (defined as institutions of higher education in the OMB Uniform Guidance at 2 CFR part 200, subpart A, and 20 U.S.C. 1001);
 - A nonprofit research entity;
 - A state or local government; or
- An entity deriving 80 percent or more of its annual revenue from Federal management and operating (M&O) contracts that are subject to agency annual site sustainability reporting requirements.

The exception provided for Federallyrecognized tribes or tribal or Native corporations is in accordance with related Federal procurement policies and current commercial norms for sustainability reporting. The exception for institutions of higher education or nonprofit research entities is provided because a large majority of such institutions that are significant or major contractors either already set GHG reduction targets and make sustainability disclosures but are likely doing so (in accordance with current commercial norms for sustainability reporting) with standards and systems other than those specified in this rule, or are pass-through entities with minimal Scope 1 and 2 emissions and

little capacity to manage Scope 3 emissions and climate risks.

An M&O contract is an agreement under which the Government contracts for the operation, maintenance, or support of a Government-owned or Government-controlled research, development, special production, or testing establishment wholly or principally devoted to one or more major programs of the contracting Federal agency (see FAR subpart 17.6). A market scan indicates that a majority of current M&O contract holders derive all, or substantially all, of their revenue from Federal site M&O contracts. For these contractors, it was determined that since all or substantially all their facilities and GHG emissions are already subject to comprehensive Federal sustainability performance and reporting requirements under their M&O contracts, related laws, and executive orders, it would be duplicative and unnecessary to require them to also report using the separate standards and systems required by this rule. The market scan indicated that a minority of current M&O contract holders are larger entities deriving less than 80 percent of their revenue from Federal site M&O contracts, indicating that they likely operate substantial facilities and emit substantial GHG emissions, which are not covered by other Federal sustainability performance and reporting requirements. For these entities, requiring them to report using the separate standards and systems required by this rule will allow the Government and the public to understand the scope of climate risks and impacts attributable to these entities' substantial non-M&O activities and encourage the entities to reduce those risks and impacts.

FAR section 23.XX04(b) provides additional exceptions for certain major contractors. If a major contractor is considered a small business for the North American Industry Classification System (NAICS) code it has identified in its SAM registration as its primary NAICS code, or if it is a nonprofit organization, then it is not required to complete an annual climate disclosure or to set science-based targets. However, the major contractor is still required to complete a GHG inventory of its Scope 1 and Scope 2 emissions and must report these total annual emissions in SAM.

The public is invited to provide public comments on the appropriateness of the exceptions included in this proposed rule, including potential alternatives to be considered in the formation of the final rule.

D. Standards

Section II.1. of OMB memorandum M-22-06 directs the FAR Council to leverage existing third-party standards and systems in the development of regulatory amendments to promote contractor attention on reduced GHG emissions and Federal sustainability. In alignment with the National Technology Transfer and Advancement Act of 1995 and OMB Circular A-119, which directs Federal agencies to use nongovernmental private sector standards to meet policy and procurement objectives, as described in section II.B. of this preamble, this rule engages contractors through widely-accepted protocols and platforms that they are already using to publicly disclose annual climate data to a variety of other interested parties. The rule requires contractors to use the following four standards: the GHG Protocol Corporate Accounting and Reporting Standards and Guidance, the 2017 Recommendations of the TCFD, the CDP Climate Change Questionnaire, and the SBTi criteria. The public is invited to provide public comments on the use of these standards in this proposed rule, including potential alternatives to be considered in the formation of the final rule. The following is a summary of the standards proposed for disclosures by significant and major contractors.

1. GHG Protocol Corporate Accounting and Reporting Standards and Guidance

The GHG Protocol Corporate Accounting and Reporting Standard, 2004 revised edition (see https:// ghgprotocol.org/sites/default/files//ghgprotocol-revised.pdf) is the most widely used accounting tool to track corporate GHG emissions. It describes how to complete a comprehensive GHG inventory across Scope 1, Scope 2, and relevant categories of Scope 3 emissions. This standard is supplemented by Required Greenhouse Gases in Inventories: Accounting and Reporting Amendment, 2013 (see https://www.ghgprotocol.org/sites/ default/files/ghgp/NF3-Amendment_ 052213.pdf). Further implementing instructions for quantifying emissions can be referenced in GHG Protocol Scope 2 Guidance, 2015 (see https:// ghgprotocol.org/sites/default/files/ standards/Scope%202%20Guidance_ Final_Sept26.pdf) and GHG Protocol Corporate Value Chain (Scope 3) Accounting and Reporting Standard Guidance, 2011 (see https:// ghgprotocol.org/sites/default/files/ standards/Value-Chain-Accounting-Reporting-Standard_041613_2.pdf). General information on the GHG

Protocol Corporate Standard and related guidance is available at https://ghgprotocol.org/corporate-standard.

2. Task Force on Climate-Related Financial Disclosures

In 2017, the TCFD launched recommendations to improve and increase reporting of climate-related financial information. The TCFD recommendations cover Governance, Strategy, Risk Management, and Metrics and Targets. Climate-related risks are considered across two major categories: (1) risks related to the transition to a lower-carbon economy, and (2) risks related to the physical impacts of climate change. Governments around the world are asking companies to provide consistent and decision-useful information to market participants in line with TCFD recommendations (see https://assets.bbhub.io/company/sites/ 60/2021/10/FINAL-2017-TCFD-Report.pdf). In 2021, the TCFD updated its implementation guidance for the 2017 Recommendations by issuing an annex titled "Annex: Implementing the Recommendations of the Task Force on Climate-related Financial Disclosures.' The updates reflect the evolution of disclosure practices, approaches, and user needs (see https://assets.bbhub.io/ company/sites/60/2021/07/2021-TCFD-Implementing_Guidance.pdf).

3. CDP Climate Change Questionnaire

CDP (formerly the Carbon Disclosure Project) is an international non-profit organization that runs a global environmental disclosure system. CDP's annual Climate Change Questionnaire enables companies to report GHG emissions and climate change risk through a standard process and make their environmental impact transparent to interested parties. Companies disclose once annually by submitting a response to the CDP Climate Change Questionnaire through CDP's online response system (ORS). Companies are able to utilize the GHG Protocol Corporate Accounting and Reporting Standard when completing their GHG inventory to disclose through CDP. CDP's disclosure platform provides the mechanism for reporting climate-related financial risks in line with the TCFD recommendations as well as reporting annual progress towards science-based

CDP operates an annual disclosure cycle that enables companies to disclose emissions and climate risk information at the request of investors, corporate and government customers, the general public, and other interested parties. Each year CDP issues the proposed updates to the questionnaire, which are

opened for public consultation in the fall (approximately September) and the finalized questionnaire and guidance are available early in the new year (approximately January). The Online Response System (ORS) opens once annually (approximately April), and responses must be submitted by a summer deadline (approximately July). Updated calendars are published by CDP annually: https://www.cdp.net/en/companies-discloser/How-to-disclose-as-a-company.

CDP's Climate Change Questionnaire prompts users for some disclosures and datapoints that are beyond the scope of this FAR rule, which is to obtain annual climate disclosures from major contractors (see II.B.2. of this preamble). These additional datapoints may be of interest to investors, external non-Federal Government customers, or the general public who also rely on CDP disclosures to evaluate corporate climate performance. This proposed FAR rule clarifies at 23.XX03(b)(1) and in 52.223-22 and 52.212-3(t) that the offeror (itself or through its immediate owner or highest-level owner) is only required to complete those portions of the CDP Climate Change Questionnaire that align with the TCFD recommendations as identified by CDP (https://www.cdp.net/en/guidance/how*cdp-is-aligned-to-the-tcfd*). This allows companies to determine what responses in the CDP questionnaire are appropriate or necessary to complete in order to provide a TCFD-aligned annual climate disclosure. Questions beyond those that are necessary to provide an annual climate disclosure for Federal use, as defined by this rule, are considered optional for the purposes of this rule. Neither the CDP climate scores, nor answers to questions beyond those necessary to provide a complete annual climate disclosure, will be used to evaluate compliance with this FAR rule. The Government seeks public comment regarding what, if any, additional specificity is needed beyond "those portions of the CDP Climate Change Questionnaire that align with the TCFD recommendations as identified by CDP (https://www.cdp.net/ en/guidance/how-cdp-is-aligned-to-the-

4. Science-Based Targets Initiative

SBTi is a partnership between CDP, the United Nations Global Compact (UNGC), the World Resources Institute (WRI), and the World Wide Fund for Nature (WWF, also known as the World Wildlife Fund). Science-based targets provide a clearly-defined pathway for companies to reduce GHG emissions in line with reductions that the latest

climate science deems necessary to meet the goals of the Paris Agreement—limiting global warming to well below 2 °C above pre-industrial levels and pursuing efforts to limit warming to 1.5 °C. Companies can commit to set a science-based target and then, within two years, must develop a science-based target and have it validated through the SBTi target validation process.

E. Starting Dates

This proposed rule acknowledges that significant and major contractors will need time to come into compliance with the new policy by including delayed starting dates. A significant or major contractor that cannot represent on or after these starting dates that it has complied with the new policy will be presumed to be a nonresponsible prospective contractor for Federal procurements (see section II.G. of this preamble).

Starting one year after publication of a final rule, a significant or major contractor (itself or through its immediate owner or highest-level owner) must have completed a GHG inventory and the significant or major contractor must have disclosed the total annual Scope 1 and Scope 2 emissions from its most recent inventory in SAM. This one-year period provides the time needed for significant or major contractors to become familiar with the GHG Protocol Corporate Accounting and Reporting Standard, to survey the GHG emissions, and for significant or major contractors to report in SAM the total metric tons of carbon dioxide equivalent (MT CO2e) of Scope 1 and Scope 2 emissions.

The compliance requirements for major contractors will start two years after publication of a final rule. This delayed starting date provides a major contractor (or its immediate owner or highest-level owner) additional time to complete a GHG inventory that covers relevant Scope 3 emissions; conduct a climate risk assessment and identify risks; complete the CDP Climate Change Questionnaire; and commit to, develop, and obtain SBTi validation of a science-based target.

F. Annual Representation

Amendments are proposed to the annual representations in the solicitation provision at FAR 52.223–22, Public Disclosure of Climate Information—Representation, and the corresponding representation in paragraph (t) of the provision at FAR 52.212–3 for acquisitions for commercial products or commercial services, to collect information on whether an offeror is in compliance

with the new policy. This provision continues to be prescribed for use only when offerors are required to be registered in SAM, though the prescription has been moved to FAR section 23.XX07 of the new subpart. All offerors that register in SAM will be required to represent on an annual basis whether they are a significant contractor or a major contractor (see section II.A. of this preamble). If an offeror represents that it is a significant or major contractor, then the offeror will be required to represent whether it—

• Is subject to an exception (see section II.C. of this preamble);

• Has completed, within its current or previous fiscal year, a GHG inventory of the annual Scope 1 and Scope 2 emissions (evidenced by a report in SAM of the total annual Scope 1 and Scope 2 emissions identified in its most recent inventory);

 Makes available on a publicly accessible website an annual climate disclosure that was completed using the CDP Climate Change Questionnaire within its current or previous fiscal year; and

• Makes available on a publicly accessible website a science-based target that has been validated by SBTi.

The new representations are intended to assist the contracting officer in determining whether the policy at 23.XX03 applies to an offeror and, if so, whether the offeror is in compliance. The new FAR section 23.XX05, Procedures, provides instructions for the contracting officer who is reviewing the representations in paragraph (d) of the provision at FAR 52.223-22 (or the equivalent representations in the commercial provision at FAR 52.212-3(t)). This section includes tables to illustrate the specific responses from offerors that are required to indicate that the offeror is in compliance. If an offeror's representations indicate that the offeror is a significant or major contractor and it is not in compliance with the policy at FAR 23.XX03 (or if the contracting officer has reason to question the representations), then the contracting officer is directed to follow the procedures at FAR 9.104–3(e) for determining whether the offeror is responsible (see section II.G. of this preamble).

G. Responsibility Determinations

Per FAR section 23.XX05(c), the contracting officer is directed to follow the procedures at FAR section 9.104—3(e) for determining responsibility when an offeror represents that it is not in compliance with the policy at 23.XX03 when it should be, or if there is reason to question the offeror's representation.

Per the new procedures at FAR 9.104—3(e), the contracting officer shall presume the prospective contractor is nonresponsible pursuant to 9.104—1, unless the contracting officer determines that—

- Noncompliance resulted from circumstances properly beyond the prospective contractor's control;
- The prospective contractor has provided sufficient documentation that demonstrates substantial efforts to comply; and
- The prospective contractor has made a public commitment to comply as soon as possible on a publicly accessible website (within one year).

In making this determination the contracting officer is directed to request information from the prospective contractor to determine what efforts it has made to comply with each requirement at FAR 22.XX03 and the basis for the failure to comply.

FAR 9.104–3(e)(3) also clarifies that a significant or major contractor who meets one of the exceptions at FAR 23.XX04 (see section II.C. of this preamble) and acquisitions that are subject to an exemption or waiver pursuant to FAR 23.XX06 (see section II.H. of this preamble) are not subject to the new responsibility standard and procedures.

H. Exemptions and Waivers

The new section at 23.XX06 provides for certain exemptions from and waivers to the new procedures for determining responsibility at 23.XX05 and the new responsibility standards at FAR 9.104-3(e) for determining whether a significant or major contractor is responsible (discussed in section II.G. of this preamble). For example, the new procedures do not apply to acquisitions listed at FAR 4.1102(a) where the offeror is exempt from the requirement to be registered in SAM at the time an offer is submitted, since enforcement of the policy at FAR 23.XX03 is accomplished via review of a significant or major contractor's representations in SAM as described in FAR section 23.XX05.

The procedures at FAR section 23.XX05 may be waived by the senior procurement executive for facilities, business units, or other defined units for national security purposes, or for emergencies, national security, or other mission essential purposes. The senior procurement executive may also provide a waiver for a period not to exceed one calendar year to enable an entity an additional year to come into compliance. An agency must make such waivers available on its agency website.

I. Definitions

Definitions of the following terms are provided in FAR section 23.XX02 and in paragraph (a) of the solicitation provisions at FAR 52.223-22 and 52.212-3: "annual climate disclosure," "GHG inventory," "major contractor," "publicly accessible website," "sciencebased target," "Scope 1 emissions," "Scope 2 emissions," "Scope 3 emissions," and "significant contractor." The definitions of "immediate owner" and "highest-level owner" that are currently included in the provision at FAR 52.212-3(a) are added to FAR section 23.XX02 and the solicitation provision at FAR 52.223-22. The current definition of "greenhouse gases" remains at FAR section 23.001 with minor spelling corrections.

J. Conforming Changes

Given that the policy on climate disclosures is moved to a new subpart at FAR 23.XX, conforming changes are proposed at FAR subpart 23.8 to remove the coverage of disclosure of GHG emissions and reduction goals. As a result, 23.802(c) and (d) and 23.804(b) are removed and the remaining paragraphs at FAR sections 23.800 and 23.804 are renumbered accordingly. A cross-reference to the new subpart is added at 23.800(b). Conforming updates to the cross-references to FAR 23.804 are also proposed in FAR 52.213-4, and the prescription references at FAR 52.223-11, 52.223-12, 52.223-20, and 52.223-21. In addition, the title of the provision at FAR 52.223-22 is updated in the provision at FAR 52.204–8, Annual Representations and Certifications, and in the list of provisions at FAR 4.1202(a).

K. Public Input

The public is specifically invited to provide public comments on the following:

- The appropriateness of the exceptions identified in section II.C. of this preamble, including potential alternatives to be considered in the formation of the final rule.
- The use of the standards identified in section II.D. of this preamble, including potential alternatives to be considered in the formation of the final rule.
- With regards to the CDP Climate Change Questionnaire discussed in section II.D.3. of this preamble, whether any specificity beyond "those portions of the CDP Climate Change Questionnaire that align with the TCFD as identified by CDP (https://www.cdp.net/en/guidance/how-cdp-isaligned-to-the-tcfd)" is necessary.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT), for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), and for Commercial Services

This rule proposes to amend the annual representation in the solicitation provision at FAR 52.223-22, Public Disclosure of Climate Information— Representation, and the corresponding representation in paragraph (t) of the solicitation provision at FAR 52.212-3, Offeror Representations and Certifications—Commercial Products and Commercial Services. The provision at FAR 52.223-22 will continue to be prescribed for use in solicitations that also include the provision at FAR 52.204–7, System for Award Management. This prescription ensures that all offerors who are required to register in SAM and who received \$7.5 million or more in Federal contract obligations in the prior Federal fiscal year, including those who compete exclusively for contracts for commercial products or commercial services or those valued at or below the SAT, provide a response to the revised representations.

The new procedures at FAR 22.XX05 and new standards at FAR 9.104 for determining the responsibility of a prospective contractor, if it is a significant or major contractor, will apply to acquisitions of commercial products (including COTS items) or commercial services, and to acquisitions valued at or below the SAT. Failure to apply the new procedures and standards for responsibility determinations to these types of acquisitions would not accomplish the intended policy objective of the Executive Order. These procedures ensure the Government is able to enforce the disclosure requirements for significant and major contractors.

IV. Expected Impact of the Rule

This rule proposes to create a new standard of responsibility. Specifically, a prospective contractor that is a significant or major contractor will be presumed to be nonresponsible unless—

• Starting one year after publication of a final rule, the significant or major contractor (itself or through its immediate owner or highest-level owner) has completed a GHG inventory of its annual Scope 1 and Scope 2 GHG emissions, and the significant or major contractor has reported the total annual Scope 1 and Scope 2 emissions from its most recent inventory in SAM at https://www.sam.gov; and

• Starting two years after publication of a final rule, a major contractor (itself or through its immediate owner or highest-level owner) has submitted an annual climate disclosure within its current or previous fiscal year by completing those portions of the CDP Climate Change Questionnaire that align with the TCFD recommendations as identified by CDP (https://www.cdp.net/en/guidance/how-cdp-is-aligned-to-the-tcfd) and has developed a science-based target and had the target validated by SBTi within the previous five calendar years.

When making a responsibility determination, a contracting officer will rely on the representation of a prospective contractor in the revised solicitation provision at FAR 52.223-22 (or the equivalent representations in the commercial provision at FAR 52.212-3(t)) regarding whether the prospective contractor is a significant or major contractor and, if so, whether it is in compliance with the new disclosure and target requirements, as applicable. If a prospective contractor's representation indicates that it is a significant or major contractor, is not subject to an exception, and is not in compliance, then the contracting officer will request additional information from the prospective contractor regarding the efforts it has made to comply before making a responsibility determination, unless an exemption or waiver applies.

A. General Compliance Requirements

1. Representations in SAM

All offerors that register in SAM will be required to represent in paragraph (d)(1) of the provision at FAR 52.223-22 (or the equivalent representations in the commercial provision at FAR 52.212-3(t)(3)(i) whether the offeror meets the definition of a significant or major contractor. An offeror is considered a "significant contractor" if the offeror received \$7.5 million or more, but not exceeding \$50 million, in Federal contract obligations in the prior Federal fiscal year. An offeror is considered a "major contractor" if the offeror received more than \$50 million in Federal contract obligations in the prior Federal fiscal year. Only offerors that represent that they are a significant or major contractor will be required to complete the remaining representations in paragraphs (d)(2) through (d)(5) of the provision at FAR 52.223-22 (or the equivalent representations in the commercial provision at FAR 52.212-3(t)(3)(ii) through (v)).

An offeror will represent in paragraph (d)(2) of the provision whether the offeror meets an exception to the new

policy per the new section at FAR 23.XX04. The contracting officer uses the offeror representations in this paragraph to determine if an offeror who represents in paragraph (d)(1) of the provision that it is a significant or major contractor is subject to the new disclosure and compliance

requirements.

The representation in paragraph (d)(3) of the provision gathers information about whether a significant or major contractor (itself or through its immediate owner or highest-level owner) has completed within its current or previous fiscal year a GHG inventory of its annual Scope 1 and Scope 2 emissions. Offerors will be required to report in this representation the total Scope 1 and Scope 2 emissions identified in its most recent GHG inventory.

The representations in paragraph (d)(4) and (d)(5) of the provision gather information regarding whether a major contractor (itself or through its immediate owner or highest-level owner) makes available on a publicly accessible website:

- An annual climate disclosure that was completed using the CDP Climate Change Questionnaire within its current or previous fiscal year; and
- A science-based target that has been validated by SBTi within the previous five calendar years.

An offeror that is a major contractor is also required to report in paragraph (e) of the provision at FAR 52.223–22 (or in paragraph (t)(4) of the commercial provision at FAR 52.212-3) the website(s) where the annual climate disclosure and validated science-based target are made publicly available. While the compliance requirements referenced in the last two representations at paragraphs (d)(4) and (d)(5) are only applicable to major contractors, both significant and major contractors will be required to complete these representations. This allows the Government to monitor whether significant contractors are taking steps to provide enhanced climate disclosures and to reduce their GHG emissions.

2. GHG Inventory

Starting one year after publication of a final rule, a significant and major contractor (or their immediate owner or highest-level owner) must follow the GHG Protocol Corporate Accounting and Reporting Standard (see section II.D.1. of this preamble) to complete a GHG inventory of the Scope 1 and Scope 2 emissions. Starting two years after publication of a final rule, major contractors will also inventory relevant Scope 3 emissions. Companies

completing a GHG inventory for the first time will often begin by reviewing accounting standards and methods, determining organizational and operational boundaries, and choosing a reporting and base year. They will collect data aligned to that year from across the business (including but not limited to fuel purchases, such as gasoline and heating oil, and electricity bills) and utilize a GHG calculator to determine the associated GHG emissions emitted across Scope 1, Scope 2, and (if applicable) relevant Scope 3 emissions expressed in MT CO2e. Companies will likely develop a GHG Inventory Management Plan to formalize data collection procedures, in order to ensure consistency on an annual basis.

3. Annual Climate Disclosure

Starting two years after publication of a final rule, a major contractor (or its immediate or highest-level owner) must provide an annual climate disclosure that aligns with the 2017 recommendations of the TCFD and the 2021 TCFD update (see sections II.B.2 and II.D.2. of this preamble). Companies following the TCFD recommendations will assess two types of climate risks: (1) transition risks associated with the transition to a lower-carbon global economy, the most common of which relate to policy and legal actions, technology changes, market responses, and reputational considerations; and (2) physical risks emanating from climate change, which can be event-driven (acute) such as increased severity of extreme weather events (e.g., cyclones, droughts, floods, and fires) as well as longer-term shifts (chronic) in precipitation and temperature and increased variability in weather patterns (e.g., sea level rise).

The major contractor (or its immediate or highest-level owner) must provide its annual climate disclosures by completing those portions of the CDP Climate Change Questionnaire that align with the TCFD as identified by CDP (https://www.cdp.net/en/guidance/how*cdp-is-aligned-to-the-tcfd*). Companies receive an invitation to disclose once annually through CDP on behalf of all investors, corporate customers, and/or Government customers requesting their response. Companies who have not received an invitation can indicate their intention to disclose as a "self-selected company (SSC)" by contacting respond@cdp.net. Companies complete and submit their response to the CDP Climate Change Questionnaire through CDP's online response system (ORS). The CDP Climate Change Questionnaire can be saved in draft form in the ORS,

exported for internal completion and review, and then submitted through the ORS prior to the relevant deadline. CDP provides detailed guidance to support companies in understanding and completing the questionnaire (see https://www.cdp.net/en/guidance/guidance-for-companies).

4. Science-Based Targets

Starting two years after publication of a final rule, a major contractor will also be required to develop (itself or through its immediate or highest-level owner) a science-based target and have the target validated by SBTi. Companies can commit to set a science-based target by submitting a letter to SBTi and will be recognized as "committed" on the SBTi website. Once committed, a company has 24 months to submit their targets to SBTi for validation. Companies independently develop their sciencebased target in line with science-based criteria (including sector-specific guidance, where relevant), which are available on the SBTi website (https:// sciencebasedtargets.org/). Companies then submit the science-based target to SBTi for validation. Validated targets are published one month after validation, unless otherwise instructed. Targets not receiving validation are provided with detailed feedback from expert reviewers and an opportunity to resubmit. Following validation, companies should disclose emissions annually and monitor progress on reaching the target.

B. Benefit

The Federal Government is the world's single largest purchaser of goods and services, spending over \$650 billion in contracts in fiscal year 2020 alone. Public procurement can shift markets, drive innovation, and be a catalyst for adoption of new norms and global standards. Requiring significant and major contractors to publicly disclose their GHG emissions and requiring major contractors to publicly disclose their climate-related financial risk and set science-based reduction targets will give visibility to major annual sources of GHG emissions and climate risks throughout the Federal supply chain and could, in turn, provide insights into the entire U.S. economy. While disclosure alone does not reduce emissions and climate risk, the expectation of increased public transparency and accountability may prompt suppliers to take action following a "what gets measured gets managed" mantra, and thus increase the resilience of the Federal supply chain.

Several discrete categories of benefits are expected from this regulation to

include: identifying areas for increased efficiency and reduced risks; understanding and reduction of supply chain vulnerabilities; aligning targets to address climate change; improved transparency, accountability, and ability of Federal agencies to collaborate with contractors; and increased efficiency of disclosure via standardization.

1. Identifying Areas for Increased Efficiency and Reduced Risks

Companies who are required to publicly disclose their GHG emissions and climate risks may be prompted to thoroughly investigate their operations and supply chains, which may, in turn, reveal opportunities to realize efficiencies and manage risks. Any efficiency improvements would, in turn, flow into the company's performance on Federal contracts. The activity data that is examined (e.g., fuel and electricity bills) to conduct a GHG inventory can reveal areas where efficiencies may be realized. After conducting a GHG inventory, many companies may choose to address sources of emissions. For example, the Federal Government's assessment of its GHG footprint has revealed the most significant areas of GHG emissions and climate risks across the Federal Government's own operations and supply chains, which prompted the Federal Sustainability Plan to establish ambitious programs to address them: zero emissions vehicles, carbon pollution free electricity, net zero buildings, and net zero procurement. Companies take widely varied approaches to managing operational efficiencies relevant to their GHG emissions, ranging from no action to opportunistic system upgrades to purchasing offsets to address emissions outside of a company's boundaries. By requiring the development, maintenance, and public disclosure of contractor GHG inventories and reduction targets, this rule may prompt contractors to undertake a comprehensive analysis of their energy and fuel use, electricity procurement, and other emissions sources (e.g., refrigerants, agricultural and industrial activities), which may prompt action to invest in GHG management opportunities across their facilities, operations, and supply chains with multi-year paybacks. Well-managed contractors may choose to voluntarily manage GHGs and cost savings, but these expanded expectations will set a level playing field for a wider range of contractors to get started.

Those contractors who choose to address GHG emissions may experience benefits in cost savings, as shown by the Government's own experience as well as

that of contractors who have voluntarily disclosed emissions. The Federal Government has tracked and publicly disclosed its Scope 1 and 2 emissions annually since 2008, while implementing targets for energy and water efficiency and emissions reduction. The Government's practice of setting and meeting these targets has led to a reduction of 32.2 percent in Federal agency emissions from standard operations since 2008, reduction in total annual energy use (including all facility and mobile sources) from approximately 1,143,000 Billion British thermal units (BBtu) in 2008 to 849,000 BBtu in 2020 (25 percent reduction), and a reduction of total annual energy costs from \$29.4 billion in 2008 to \$17.1 billion in 2020 (reduction of \$12.3 billion annually, or 41.8 percent, in inflation-adjusted dollars). Similarly, in 2021, companies (including, but not limited to, Federal contractors) disclosing emissions and climate risk through the CDP disclosure system independently reported emissions and cost savings from emissions reduction activities implemented in the given reporting year; in aggregate, these benefits collectively amounted to 1.8 billion metric tons (MT) CO2e in emissions reductions with over \$29 billion in associated cost savings for those suppliers. Public disclosure of this information in a standardized format creates a global database that can be utilized for tracking year-over-year progress, sharing ideas among companies with similar emissions profiles, and enabling benchmarking of performance.

2. Understanding and Reduction of Supply Chain Vulnerabilities

In accordance with E.O. 14030, this proposed rule would require major contractors who have a significant share of Government business to identify their climate-related financial risks, including physical and transition risks. These risks could impact the contractor's business operations in the short, medium, and long-term. The required disclosures will prompt entities to investigate and understand these risks, develop plans to mitigate them, and communicate the risks and mitigation plans to the public and Federal agencies. These disclosures will enable the Government to understand how and when the risks faced by major contractors (some of which are missioncritical) and their supply chains, including but not limited to increased likelihood of disruptive climate and weather events and material and energy cost fluctuations, may impact the agencies' own missions and activities.

This understanding will increase the effectiveness of the Federal supply chain by enabling agencies to develop and improve their own plans to safeguard their assets and missions, ensuring uninterrupted provision of critical services to the U.S. public. Currently, the Federal Government and general public have significantly reduced visibility into the preparedness of major contractors upon whom the Government relies on for products and services (some of which are critical). For example, per a U.S. Government Accountability Office report (GAO-16-32, Federal Supply Chains: Opportunities to Improve the Management of Climate-Related Risks), in October 2012, Superstorm Sandy caused widespread damage to logistics and transportation networks throughout the Northeast, leading to major fuel shortages for agencies to overcome while providing critical Federal services, such as disaster relief and mail delivery, and causing an estimated \$70 billion in direct damages and lost economic output.

Mitigating the effects of climate change by reducing emissions can provide important economic, ecological, and social benefits by significantly reducing major risks to the U.S. economy. According to the U.S. Fourth National Climate Assessment (see Key Message 2, Chapter 29) published by the U.S. Global Change Research Program in 2018, a Congressionally mandated, joint report of thirteen U.S. agencies with research programs and expertise on changes in the global environment and their implications for society:

In the absence of more significant global mitigation efforts, climate change is projected to impose substantial damages on the U.S. economy, human health, and the environment. Under scenarios with high emissions and limited or no adaptation, annual losses in some sectors are estimated to grow to hundreds of billions of dollars by the end of the century. It is very likely that some physical and ecological impacts will be irreversible for thousands of years, while others will be permanent.

3. Aligning Targets To Address Climate Change

The Federal Government has committed to reducing its Scope 1, 2, and 3 GHG emissions, including those associated with Federal procurement activities, to achieve a net zero economy by 2050. As the single largest purchaser in the world, Federal procurement represents both a substantial contribution to climate change emissions and a significant opportunity to reduce them. GSA has estimated that emissions from contractors performing Federal contracts are significantly

greater (150 million MT CO2e in Fiscal Year 2019) than emissions from Federal buildings and non-tactical fleets (37 million MT CO2e) (see https:// www.gsa.gov/Governmentwideinitiatives/Federal-highperformancegreen-buildings/resource-library/ sustainable-acquisition). The Federal Government has committed to a 65 percent reduction in its Scope 1 and 2 operational emissions by 2030 (from 2008 levels), demonstrating it is doing its part via internal operations to achieve the U.S. Nationally Determined Contribution of a 50-52 percent economy-wide reduction in emissions by 2030. In order to similarly reduce its much greater Scope 3 emissions, the Federal Government's best solution is to require that its major contractors quantify their GHG emissions and set science-based targets to align ambitions and identify areas for collaboration on shared goals.

According to the EPA, in addition to global or national economic benefits, forward thinking organizations also recognize internal benefits of setting and publicly disclosing GHG reduction targets, including increasing senior management attention and funding for investing in GHG reduction projects, encouraging innovation, improving employee morale, and helping to recruiting and retain qualified employees (see https://www.epa.gov/ climateleadership/target-setting). CDP's 2021 post-disclosure survey found that 76 percent of responding companies say climate disclosure helps "boost their competitive advantage" and 86 percent say that "protecting and improving the reputation of my organization" is an important benefit of disclosure (see https://www.cdp.net/en/companiesdiscloser).

More than 3,600 companies globally, representing over one third of the global economy's market capitalization, have voluntarily committed to setting science-based targets for reducing emissions (see https://sciencebased targets.org/). A 2018 survey of 185 company executives from SBTicommitted businesses found that 79 percent of companies experienced a brand reputation boost, 63 percent saw an increase in innovation, 55 percent reported that preparing for a low-carbon transition led to a newly earned competitive advantage (see https:// sciencebasedtargets.org/blog/sixbusiness-benefits-of-setting-sciencebased-targets). Companies with targets validated by SBTi are reducing emissions at an accelerating pace, collectively achieving 12 percent Scope 1 and 2 emissions reduction in 2020 and a total emissions decrease of 29 percent

between 2015 and 2020. According to SBTi's science-based target setting methodologies, an annual emissions reduction of at least 4.2 percent is required to align organizations with the Paris Agreement goal of 1.5°C maximum global temperature rise (see https:// sciencebasedtargets.org/reports/sbtiprogress-report-2021). Requiring that major contractors set, disclose, and maintain validation of such ambitious climate targets can thus be an effective tool for addressing the Federal Government's Scope 3 emissions and associated risks of climate change to the national economy, while providing economic and other benefits to the contractors themselves.

4. Improved Transparency, Accountability, and Ability To Collaborate With Suppliers

Without knowledge of existing "hot spots" (emissions-intensive sectors and activities) and cost-effective emissions reduction opportunities, it may be difficult for Federal agencies and contractors to understand where to start in seeking to reduce emissions, how to prioritize emissions reduction programs and activities, and how much to invest in each. Public disclosure provides transparency into the historical costs and impacts of organizational strategies and activities, the current management strategies of peer and partner organizations, and their future-focused targets. Disclosure of climate risks and management strategies enables benchmarking and collaborative opportunities (1) between Federal contractors and (2) between contractors and the Government, thereby increasing economy of efforts. Public disclosures thus benefit collective accountability for the shared challenge of addressing climate change throughout the global economy and enable transparent tracking of progress over time.

Furthermore, for companies with significant Scope 3 emissions, supply chain engagement can be an opportunity for further efficiency, collaboration and innovation. In 2021, of the 13,000 companies reporting through CDP, 71 percent of companies reported their Scope 1 and 2 emissions, while only 20 percent reported emissions associated with products and goods they purchase (Scope 3). However, Scope 3 emissions for a company are, on average, over 11 times higher than operational emissions. Companies can calculate Scope 3 emissions using a hybrid approach of disclosed and modeled data that improves over time as data quality and supplier engagement improve. Only 38 percent of companies who disclose through CDP currently report that they

engage their own suppliers on sustainability, however those who do engage suppliers realize significant cost and emissions savings; companies engaging their suppliers through CDP resulted in a reduction of 231 million tons of CO2e in 2021. Supplier engagement represents an opportunity for many companies to drive additional benefits for the Federal government and national economy by encouraging contractors to work with their suppliers, contractors, and other entities in their supply chains to identify cost-effective ways to reduce emissions. Through this rule, the Federal Government will communicate to its prospective contractors and their supply chains that transparent disclosure and management of supply chain GHG emissions and climate risk can be a matter of social license to operate and contractual access to important customers, thus multiplying the potential for reducing energy costs and associated emissions.

5. Increased Efficiency of Disclosure via Standardization

In addition to the above benefits, this rule will lead to increased efficiency in the processes and industries by which major contractors disclose climate related financial risks. By aligning with global standards such as the TCFD recommendations and SBTi targetsetting methodologies, as well as the leading centralized data platform CDP (which implements and is aligned with TCFD), this rule will reinforce existing industry trends toward standardization around these systems, which are already used by large numbers of U.S. companies because they are required in order to meet the demands of other entities, such as non-Federal customers and investors. The standards and systems required by this rule will thus allow affected companies to develop disclosures that efficiently meet multiple requirements for Federal procurement (this rule), access to capital markets (investors' needs), and other existing market requirements (such as ratings and rankings systems). Much of this standardization to date has occurred outside of the Federal Government, led by NGOs, investors, companies and ratings and rankings platforms as well as cities, states, and other national governments. As discussed in section I. of this preamble, the SEC recently proposed a regulation that if adopted would require similar annual disclosures of climate related financial risk for SEC registrants, including publicly listed/traded companies, many of whom are also Federal contractors. To the extent that there may be alignment between the

SEC's proposed rule and this rule if both are adopted, companies making these disclosures and users of the information (e.g., the Federal Government, investors, and other entities) will benefit from

greater standardization of climaterelated disclosures.

C. Estimated Public Costs

The total estimated public costs associated with this FAR rule in

millions over a ten-year period (calculated at a 3-percent and 7-percent discount rate) are as follows:

Estimated costs	3% Discount rate	7% Discount rate
Present Value	\$3,935 461	\$3,262 464

The following is a summary from the Regulatory Impact Analysis (RIA) of the estimated costs impact for each general compliance requirement on significant and major contractors (see section II.A. of this preamble). The full RIA is available at https://www.regulations.gov (search for "FAR Case 2021-015" click "Open Docket," and view "Supporting Documents"). The RIA includes a detailed discussion of the assumptions and methodologies used to estimate the cost of this regulatory action, including the specific impact and costs for small businesses. On March 15, 2021, the SEC's Acting Chair Allison Herren Lee posted a request for information (RFI) on costs associated with preparation of annual climate disclosures for consideration in the development of their proposed rule (see discussion in section I of this preamble). Several respondents to the RFI provided specific cost data for companies that currently provide annual climate disclosures that align with the TCFD or other voluntary disclosure frameworks. Additionally, consulting firms submitted information on prices charged for associated climate consultant services. The cost information considered by the SEC in their proposing release was used to estimate the potential costs of this proposed FAR rule. This includes information provided in response to the RFI and information from the impact assessment produced by the United Kingdom (UK) Department for Business, Energy & Industrial Strategy, as part of its Green Finance Strategy, for a UK rule that requires certain TCFD-aligned disclosures from suppliers (see https:// assets.publishing.service.gov.uk/ Government/uploads/system/uploads/ attachment_data/file/1055931/tcfdfinal-stage-ia.pdf).

1. Regulatory Familiarization

Regulatory familiarization includes the amount of time and effort it takes a company to become familiar with the requirements of the proposed rule and the references standards. A page count of the rule, the various standards, the CDP Climate Change Questionnaire, and

the SBTi Guidance is used to calculate the cost for regulatory familiarization. We assume individuals who review the documents will spend 6 minutes per page. Significant contractors (regardless of business size) and major contractors that are small businesses will be required to become familiar with the requirements of this rule and the GHG Protocol Corporate Standard (except Scope 3 guidance). The total page count is 360 pages, which take 36 hours per person to review (360 pages * 0.1 hours/ page). Major contractors that are other than small business will be required to become familiar with the rule and all GHG Protocol, TCFD, CDP, and SBTi guidance referenced in this rule. The total page count is 967 pages, which take 97 hours per person to review (967 pages * 0.1 hours/page rounded to the nearest whole number). The per entity and total costs are summarized as follows:

- For a significant contractor that is other than a small business, it is estimated that 1 manager at a rate of \$94 per hour, 1 management analyst at a rate of \$77 per hour, and 2 business specialists at a rate of \$61 per hour will review the relevant documents, a total cost of \$10,548 per contractor. The total estimated cost for regulatory familiarization in the first year of implementation is \$16,644,744 (1,578 contractors * \$10,548/contractor).
- For a significant contractor that is a small business, it is estimated that 1 manager and 1 management analyst will review the relevant documents, a total cost of \$6,156 per contractor. The total estimated cost is \$17,452,260 (2,835 contractors * \$6,156/contractor).
- For a major contractor that is other than a small business, it is estimated that 1 manager, 2 management analysts, and 4 business specialists will review the relevant documents, a total cost of \$47,724. The total estimated cost is \$46,005,936 (964 contractors * \$47,724/contractor).
- For a major contractor that is a small business, it is estimated that 1 manager and 1 business specialist will review the relevant documents, a total

cost of \$8,928 per contractor. The total estimated cost is \$17,452,260 (389 contractors * \$8,928/contractor).

2. Annual Representations

All 491,690 entities that are registered in SAM as interested in pursuing Government contracts, of which 364,290 entities are considered small for their primary NAICS code, will be required to complete the first representation in SAM for the provision at FAR 52.223-22(d)(1) and/or the commercial provision at FAR 52.212-3(t)(3)(i) regarding whether they meet the definition of a significant or major contractor. It is estimated that, on average for each registration, it will take a business specialist six minutes at an hourly rate of \$61 to determine whether they meet the definition of a significant or major contractor. The total estimated annual cost is \$2,999,309 (491,690 registrants * 0.1 hours/registrant * \$61/ hour), of which \$2,222,169 is attributed to 364,290 small businesses. The estimated cost to complete the representation is the same in subsequent

The 5,766 significant and major contractors expected to be impacted by this rule will be required to complete the remaining representations regarding whether the offeror meets an exemption and whether the offeror (itself or through its immediate owner or highestlevel owner) has completed the GHG inventory of scope 1 and 2 emissions, made an annual climate disclosure via CDP, and set science-based targets. It is estimated that, on average for each registrant, it will take a business specialist one hour to complete the remaining representations. The total estimated annual cost is \$351,726 (5,766 registrants * 1 hour/registrant * \$61/ hour), of which \$196,664 is attributed to 3,224 small businesses. The estimated cost to complete the representations is the same in subsequent years.

3. GHG Inventory of Scope 1 and 2 Emissions

The following is a summary of the costs for significant contractors

(regardless of size) and major contractors (small businesses only) to complete inventories of their Scope 1 and Scope 2 emissions. It is expected that a contractor will use a mix of internal personnel and external consultants to complete the annual greenhouse gas inventory. Internal personnel costs include the cost for contractor employees to gather, compile, and review GHG emissions data. A contractor may use external consultants to assist with, and advise on, GHG inventories. It is also assumed that contractors will see a 25 percent reduction in burden after the first year of implementation.

For a significant contractor that is other than a small business, it is estimated that it takes two business specialists 40 hours each at an hourly rate of \$61 to gather information, one management analyst 20 hours at an hourly rate of \$77 to process and compile the information, and one senior manager 2 hours at an hourly rate of \$94 to review the compiled information. It is estimated that a significant contractor that is other than a small business will require approximately 409 external consultant hours at an hourly rate of \$104. The total estimated cost per entity is \$63,868 in the initial year of implementation and \$47,983 annually thereafter.

For significant and major contractors that are small businesses, it is estimated that it will take half as much time to conduct a GHG inventory, or 20 hours for one business specialist, 10 hours for one management analyst, and 1 hour for one senior manager. These contractors are also estimated to require approximately 153 external consultant hours. The total estimated cost per entity is \$24,724 in the initial year of implementation and \$18,640 annually thereafter.

Therefore, for the 1,578 other than small business significant contractors, the total estimated cost to conduct Scope 1 and 2 GHG inventories is \$100,783,704 (1,578 contractors * \$63,868/contractor) in the initial year of implementation and \$75,717,174 (1,578 contractors * \$47,983/contractor) annually thereafter. For the 2,835 significant contractors and 389 major contractors that are small businesses, the total estimated cost is \$79,710,176 (3,224 contractors * \$24,724/contractor)

in the initial year of implementation and \$60,095,360 (3,244 contractors * \$18,640/contractor) annually thereafter.

4. Annual Climate Disclosure and Science-Based Targets

The estimate of internal and external costs for major contractors that are other than small businesses to prepare an annual climate disclosure, submit the disclosure via the CDP Climate Change Questionnaire, set a science-based target, and have the target validated by SBTi, is based on cost information shared by respondents in response to the RFI. The RIA available at https:// www.regulations.gov (search for "FAR Case 2021-015" click "Open Docket," and view "Supporting Documents") includes a summary of the respondent information and assumptions made to estimate these costs. As stated in the SEC proposed rule, the respondents to the RFI provided information on general costs for climate disclosures. Some respondent estimates included costs for activities not covered by this rule, which is similar to the FAR rule. Other respondents provided an aggregate cost estimate making it difficult to determine how representative the costs are. Actual costs for individual contractors impacted by this rule may vary significantly depending on the contractor's size, industry, business model, corporate structure, level of experience with climate disclosures, etc.

Approximately 671 of the 964 major contractors that are other than small businesses currently represent that they do not publicly disclose information about their emissions or reduction goals. As such, it is assumed that these contractors have no experience with climate disclosures or targets. It is estimated that these contractors will have internal personnel costs of approximately \$257,103 and external consultant costs of approximately \$201,600, a total of \$458,703 per contractor in the first year of implementation. The estimated annual cost after the first year is \$412,825, a 10 percent reduction. These contractors will also be required to pay a \$9,500 fee for SBTi to validate their science-based target every five years, an annualized cost of \$1,900 per year. Therefore, the total estimated cost for these major contractors is \$309,064,613 (671 * \$460,603/contractor) in the initial year

of implementation, and \$278,280,475 (671 * \$414,725/contractor) annually thereafter.

Of the 964 major contractors that are other than small business. approximately 293 represent that they do publicly disclose information about their emissions. An analysis of the websites reported by these major contractors indicates that there are 122 distinct disclosures associated with these 293 contractors. In other words, of the 293 contractors, approximately 42 percent appear to be disclosing data attributed to (or compiled by) their immediate or highest-level owner, whereas the other 58 percent are performing the calculations and compiling the climate disclosures directly. Given that these major contractors (or their owners) already have policies and procedures in place to inventory and publicly disclose their emissions (and in many cases to also set and disclose reduction goals), the burden associated with complying with this FAR rule is estimated to be 50 percent of the cost of starting with no prior disclosure experience. Therefore, it is estimated that the internal personnel and external consultant costs associated with these disclosures is approximately \$229,390 in the first year of implementation and \$206,451 annually thereafter. The \$9,500 SBTi fee for validation of the science-based target also applies. Therefore, the total estimated costs attributed to this rule for the major contractors that currently disclose either themselves or through an immediate or highest-level owner is \$28,217,380 (122 disclosing entities * \$231,290/entity) in the initial year of implementation and \$25,418,822 (122 disclosing entities * \$208,351/entity) annually thereafter.

5. Summary of Public Costs

The total estimated cost of compliance with this proposed rule is \$604,702,840 in the initial year of implementation and \$442,826,866 annually thereafter.

D. Estimated Government Costs

The total estimated Government costs associated with this FAR rule in millions over a ten-year period (calculated at a 3-percent and 7-percent discount rate) are as follows:

Estimated costs	3% Discount rate	7% Discount rate
Present Value	\$10 1	\$8 1

This is a summary of the costs associated with this proposed rule. Additional information on this cost estimate in the RIA available at https://www.regulations.gov (search for "FAR Case 2021–015" click "Open Docket," and view "Supporting Documents").

1. Updates to SAM

The Government will be required to update the representations associated with FAR 52.223–22 and 52.212–3 in SAM. The adjustment to the representation is considered a medium level of effort that will cost approximately \$260,000 to complete.

2. Workforce Development

Government contracting officers will need to become familiar with the new policy at FAR 23.XX, the new standard of responsibility at FAR 9.104, and the representations in the provisions at FAR 52.223-22 and 52.212-3. The procedures at FAR 23.XX05 provides tables to help contracting officers evaluate offeror representations. Similarly, FAR 9.104-3(e) includes information on the type of information a contracting officer should request from an offeror that represents that it is in compliance with the new policy and the minimum requirements that must be met in order to determine a contractor responsible. No specialized training is required for Government contracting officers. The requirement to remain current on policies for Government procurement, such as changes to the FAR, is considered a part of the normal duties of contracting personnel. As such, this analysis does not quantify the time and effort for contracting officers to become familiar with the rule. In addition, there are Federal resources allocated to assisting small businesses in procurement, particularly in the Small Business Administration. It is acknowledged that this there is time and effort for these Federal workforces to become familiar with the rule or the tools available and to assist contractors with compliance, though those potential burden hours and costs are not quantified.

3. Responsibility Determinations

Starting one year after publication of a final rule, Government contracting officers will begin validating prospective contractor representations for FAR 52.223–22(d) and 52.212–3(t)(3) to ensure that significant and major contractors have completed the GHG inventory of Scope 1 and 2 emissions. Starting two years after publication of a final rule, contracting officers will also validate that major contractors have completed annual climate disclosures

and set a science-based targets. For each award, the contracting officer will log into https://www.sam.gov, search "Entity Information" for the prospective contractor, select the prospective contractor's registration, click on "Reps and Certs," and (depending on the type of acquisition) click on FAR 52.212-3 or 52.223-22 to view the offeror's representations. If the prospective contractor represents that it is a significant or major contractor, then it must complete all of the remaining representations in the solicitation provision. The contracting officer may use the tables at FAR 23.XX05, Procedures, to assist in determining whether the prospective contractor is subject to an exception and, if not, whether the prospective contractor complies with the policy. Per FAR 23.XX05(c), a contracting officer may rely on these representations when making a responsibility determination, unless the contracting officer has reason to question the representation. If a representation indicates noncompliance, then the contracting officer will request additional information from the prospective contractor to assist in making a responsibility determination.

It is not possible to quantify how often contracting officers will need to request additional information from prospective contractors. Most offerors registering in SAM will represent that they are not a significant or major contractor. It is expected that the majority of significant and major contractors will represent that they are in compliance with the new policy. While it will take longer for a contracting officer to review the representations for a significant or major contractor, it is estimated that it will take the contracting officer three minutes to review most representations. According to FPDS data for FY 2021, there were approximately 276,467 awards valued over the micro-purchase threshold, where contracting officers would be required to make a responsibility determination prior to awarding a contract. We assume that the majority of responsibility determinations are made by a GS-12/ step 5 contracting officer at a loaded rate of \$66 per hour. Therefore, the total estimated cost is \$912,341 (276,467 awards * 0.05 hours/award * \$66/hour).

4. Policy Development

Contract policy offices for Government departments and agencies will need to develop procedures for requesting senior procurement executive (SPE) approval of waivers in accordance with FAR 23.XX06(b). Specifically, the SPE approve a waiver for specific facilities, business units, or other defined units for national security purposes or for emergencies, national security, or other mission essential purposes. In addition, the SPE may approve a waiver to enable a significant or major contractor to come into compliance with the policy at 23.XX03 for a period not to exceed 1 calendar year. Such waivers must be made publicly available on the agency's website. Developing policies and procedures to support the contracting activities of a department or agency are considered a part of the normal course of doing business for contract policy offices. As such, this analysis does not quantify the time and effort for contracting officers to become familiar with the rule.

5. Analysis of Annual Climate Disclosures

The Government will also use the disclosures made pursuant to this FAR rule to inform development of policies and programs to reduce climate risks and GHG emissions associated with Federal procurement activities, and to incentivize and enable technologies critical to achieving a national economy and industrial sector that are resilient to the physical and transition risks of climate change and net zero emissions by 2050. As stated in OMB Memo M-22-06, to assist the Federal Government in assessing the results of efforts to reduce supply chain emissions, and as requested by CEQ and OMB, GSA will provide periodic recommendations on further actions to reduce supply chain emissions, based on information and data collected through supplier disclosures pursuant to this FAR rule and other publicly available information. The estimated annual cost for the Government to obtain a report of the data disclosed to CDP is \$47,000. GSA further estimates that the annual cost to analyze the data provided is approximately \$200,000.

6. Summary of Government Costs

The total estimate cost to the Government in the initial year of implementation is \$1,419,341. This includes the costs to update SAM, for reviewing offeror representations, and analyzing annual climate disclosure information. In subsequent years, the estimate cost to the Government is \$1,159,341, which includes only the cost for reviewing offeror representations and analyzing annual climate disclosure information.

E. Total Estimated Costs

The total estimated overall costs associated with this FAR rule in

millions over a ten-year period (calculated at a 3-percent and 7-percent discount rate) are as follows:

Estimated costs	3% Discount rate	7% Discount rate *
Present Value	\$3,945 462	\$3,270 466

^{*}Total of Government and public costs is higher due to rounding.

F. Alternatives Considered

The Government considered other mechanisms for enforcement of the compliance requirements. One alternative was to use a contract clause to require submission of the GHG inventory, annual climate disclosure, and validated science-based target as a deliverable under Government contracts. However, given the intent to require disclosure at the entity-level, disclosure on a contract-by-contract basis is not appropriate.

The Government also considered making noncompliance a go/no-go decision for award. In this alternative, a significant or major contractor would be ineligible for award of Government contracts unless the significant or major contractor represents that it complies with the new policy. The Government ultimately determined that treatment of contractor compliance as a matter of responsibility, not only establishes the Government's position that responsible contractors take action to address and reduce climate-related financial risk, but also allows contracting officers some flexibility to determine what actions a noncompliant contractor has taken to comply.

The Government also considered the following thresholds when establishing a definition of "major Federal supplier," the term used in E.O. 14030: \$7.5 million, \$50 million, and \$250 million. The Government also considered whether the threshold should be based on the total Government contract award value, or the total Government contract funds obligated. Currently, many larger Federal suppliers provide some disclosure, but few set science-based targets. Even fewer smaller suppliers disclose GHG emissions and climaterelated risk, and science-based targets are very rare. Ultimately, the Government settled on dual thresholds to ensure smaller Federal suppliers (i.e., "significant contractors" with \$7.5 million to \$50 million in obligations in the prior FY) take steps to understand their GHG emissions and the larger Federal suppliers (i.e., "major contractors" with more than \$50 million in obligations in the prior FY) take steps

to disclose climate-related financial risks and to reduce their GHG emissions.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is anticipated to be an economically significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

VI. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD, GSA, and NASA will send the rule and the "Submission of Federal Rules Under the Congressional Review Act" form to each House of the Congress and to the Comptroller General of the United States. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This proposed rule is anticipated to be a major rule under 5 U.S.C. 804.

VII. Regulatory Flexibility Act

DoD, GSA, and NASA expect this rule may have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601–612. An Initial Regulatory Flexibility Analysis (IRFA) has been performed and is summarized as follows:

DoD, GSA, and NASA are proposing to amend the FAR to implement section 5(b)(i) of E.O. 14030, Climate-Related Financial Risk. Section 5(b)(i) of the E.O. directs the Federal Acquisition Regulatory Council to ensure that major Federal suppliers publicly disclose their greenhouse gases and climaterelated financial risk and set science-based targets.

The objective of this rule is to implement the E.O. by creating a new FAR subpart at 23.XX, which establishes the requirement for a major Federal supplier to publicly disclose certain climate information. For the purposes of this rule, a major Federal supplier is categorized as either a significant contractor or a major contractor. A significant contractor is an offeror who received \$7.5 million or more, but not exceeding \$50 million, in Federal contract obligations in the prior Federal fiscal year. A major contractor is an offeror who received more than \$50 million in Federal contract obligations in the prior Federal fiscal year. The legal basis for this rule is 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

Per the new policy proposed at 23.XX03, a contracting officer will presume that an offeror who is a significant or major contractor is nonresponsible unless—

- Starting one year after publication of a final rule, the significant or major contractor (itself or through its immediate owner or highest-level owner) has completed a GHG inventory of the annual Scope 1 and Scope 2 GHG emissions within its current or previous fiscal year, and the significant or major contractor has reported the total annual Scope 1 and Scope 2 emissions from its most recent inventory in SAM at https://www.sam.gov; and
- Starting two years after publication of a final rule, the major contractor (itself or through its immediate owner or highest-level owner) has submitted an annual climate disclosure within its current or previous fiscal year by completing those portions of the CDP Climate Change Questionnaire that align with the TCFD and has developed a science-based target and had the reduction target validated by SBTi within the previous five calendar years.

This proposed rule provides exceptions at FAR 23.XX04(a). A significant or major contractor is not required to complete a GHG inventory of Scope 1 and Scope 2 emissions, if it is one of the following: an Alaska Native Corporation, a Community Development Corporation, an Indian tribe, a Native Hawaiian Organization, or a Tribally owned concern, as those terms are defined at 13 CFR 124.3; a higher education institution (defined as institutions of higher education in the OMB Uniform Guidance at 2 CFR part 200, subpart A, and 20 U.S.C. 1001); a nonprofit research entity; or, an entity deriving 80 percent or more of its annual revenue from Federal M&O contracts that are subject to agency annual site sustainability reporting requirements. Per 23.XX04(b), a major

contractor who is registered in SAM as a small business for its primary NAICS code or is a nonprofit organization, is exempt from the requirement to complete an annual climate disclosure and to set a science-based target.

This proposed rule will revise the annual representations in the provisions at FAR 52.223–22 and 52.212–3 to collect information a contracting officer will need to determine whether an offeror is a significant or major contractor is in compliance with the new policy. The contracting officer will follow the proposed procedures at FAR 23.XX05 and FAR 9.104–3(e) when making the responsibility determination.

According to SAM, as of January 2022, 491,690 entities are registered in SAM, of which approximately 364,290 (74 percent) were registered as small for their primary NAICS code. According to award data available in FPDS for FY 2021, there were approximately 4,413 entities that meet the definition of a significant contractors and are not subject to an exception, of which 2,835 (64 percent) are estimated to be small businesses. There were approximately 1,353 entities that meet the definition of a major contractor, of which 389 (29 percent) are estimated to be small businesses.

SAM registrants will be required to complete annual representations and

certifications in SAM will be required to complete the first representation in FAR 52.223-22(d)(1) (or the equivalent representation in the commercial provision in FAR 52.212-3(t)(3)(i)) regarding whether the registrant meets the definitions of a significant or major contractor. A registrant that represents that it is a significant or major contractor, will be required to complete the remaining representations in FAR 52.223-22(d)(2) through (5) (or equivalent representations in FAR 52.212-3(t)(3)(ii) through (v)) regarding whether they have conducted a GHG inventory, made an annual climate disclosure, and a set science-based target. Starting one year after publication of a final rule, significant or major contractors will be required to have conducted (itself or through its immediate or highest-level owner) within its current or previous FY a GHG inventory of its annual Scope 1 and 2 emissions and reported in SAM the results of its most recent inventory.

A significant or major contractor that represents that it has not conducted a GHG inventory of its annual Scope 1 and Scope 2 emissions or has not provided the results of the most recent inventory in SAM, will be presumed to be a nonresponsible prospective contractor. In such cases the contracting officer will follow the proposed procedures at FAR 9.104–3(e) and seek information from

the significant contractor on the efforts it has made to comply before making a responsibility determination. Per the existing procedures at FAR 9.104–3(d)(1), upon making a determination of nonresponsibility with regard to a small business concern, the contracting officer shall refer the matter to the Small Business Administration, which will decide whether to issue a Certificate of Competency (see FAR subpart 19.6).

A RIA has been prepared for this proposed FAR rule, which includes a detailed discussion and explanation about the assumptions and methodology used to estimate the cost of this regulatory action, including the specific impact and costs for small businesses. Costs for small businesses expected to be impacted by this rule include the cost of regulatory familiarization, completing the annual SAM representations, and conducting the Scope 1 and 2 GHG inventory each year. The total estimated cost to small businesses is \$103,054,261 (17 percent of the total estimated public costs) in the initial year of implementation and \$62,514,193 (14 percent of the total estimated public cost) in subsequent years. The following is a summary of the estimated cost of per entity for small business significant and major contractors:

ESTIMATED COST OF COMPLIANCE PER ENTITY

Entity type	Significant	contractor	Major co	ntractor
Compliance requirement	Initial year	Subsequent years	Initial year	Subsequent years
Familiarization First SAM Rep Other SAM Reps GHG Inventory	\$6,156 6 61 24,724	N/A \$6 61 18,640	\$8,928 6 61 24,724	N/A \$6 61 18,640
Total Cost	30,947	18,707	33,719	18,707

A summary of the RIA is provided in section IV. of this preamble. The full RIA is available at https://www.regulations.gov (search for "FAR Case 2021–015" click "Open Docket," and view "Supporting Documents").

The SEC is proposing to require climaterelated financial risk disclosures from SEC registrants, including publicly listed/traded companies (see 87 FR 21334, April 11, 2022). Both the SEC proposed rule and the FAR proposed rule leverage the GHG Protocol Corporate Accounting and Reporting Standard; therefore, the rules are considered to be in alignment. Per the exceptions at FAR 23.XX04(b), the requirement to provide an annual climate disclosure and set a sciencebased target is not applicable to a company that is registered in SAM as a small business for its primary NAICS code.

The burden imposed on small entities is the minimum necessary to implement the requirements of section 5(b)(i) of E.O. 14030. To minimize the burden on Federal contractors, this rule leverages standards that are widely used by companies to inventory their GHG emissions and analyze their climate risks. Efforts were also taken to align

with the approach of the SEC proposed rule, which further minimizes burden for small businesses. As a result of this rule, a small business that received \$7.5 million in Federal contract obligations in the prior Federal fiscal year is considered a significant contractor and will be required to complete the GHG inventory of Scope 1 and Scope 2 emissions. However, those entities that received more than \$50 million in Federal contract obligations in the prior Federal fiscal year (a major contractor) and are registered in SAM as a small business for their primary NAICS code are exempt from the requirement to complete an annual climate disclosure and set a science-based target. Several alternatives were considered but not accepted as they would not accomplish the intended policy objective of the E.O. The alternatives considered include:

• Exemption for small business. One alternative considered was an exemption for small businesses who are significant contractors from the requirement to inventory and publicly disclose their Scope 1 and 2 emissions. It was determined that the limited Scope 1 and 2 reporting will be beneficial for these small businesses and the

Government. By inventorying their Scope 1 and 2 emissions, small businesses—including those that are not "carbon intensive" can find opportunities to minimize climate risks both in their operations and their own supply chains. This rule will also prepare these small businesses to respond to requests for similar data from customers besides the Federal Government. It is also beneficial for the Government to collect this data from these small businesses to have a more complete understanding of the impact of GHG emissions on the Federal supply chain and to calculate its own emissions and set its own reduction targets.

• Delayed or rolling compliance dates. Another alternative considered was a delay in the effective date of the Scope 1 and 2 reporting requirements for small business significant contractors. Consideration was given to a two-year delay, or a rolling effective date based on Federal contract obligations in the prior fiscal year. Ultimately, it was determined that given the widely adopted and simple exercise of quantifying Scope 1 and 2 emissions, and the E.O. target of a net-zero emissions economy by no later than 2050, it may be confusing

to have separate tiers and timelines for significant contractor reporting while failing to advance the E.O.'s stated goals. Furthermore, since GHG emissions inventory occurs once a year retroactively based on the previous year's data, no additional actions or changes to business practice would need to be taken to prepare for this reporting, and thus there would be no minimized burden from a delay.

• Use other sources of data. Other sources of data on Scope 1 and 2 emissions were also considered, such as current CDP data, corporate websites, and/or corporate reports. Third party "modeled emissions" using industry averages were also considered. However, it was determined that this alternative would not advance the stated target of the E.O. for a variety of reasons: the lack of standardization, reduced accuracy of models to capture the actual business practices unique to producing goods and services for the Federal Government, and the lack of GHG emissions reporting by many small businesses. Furthermore, the burden to comply with this proposed rule for small businesses who currently inventory their GHG emissions will be extremely low, only requiring two numbers the entity has already generated (or are easily calculated using free Excel tools) to be entered into SAM.

The Regulatory Secretariat Division has submitted a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the IRFA may be obtained from the Regulatory Secretariat Division. DoD, GSA, and NASA invite comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD, GSA, and NASA will also consider comments from small entities concerning the existing regulations in subparts affected by the rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (FAR Case 2021–015), in correspondence.

VIII. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501–3521) applies because the proposed rule contains information collection requirements. Accordingly, the Regulatory Secretariat Division has submitted to OMB a request for approval of a revision to "OMB Control Number 9000–0107, Federal Acquisition Regulation Part 23 Requirements" concerning the information collection requirements in the provision at FAR 52.223–22 or its equivalent at FAR 52.212–3(t).

A. Public Reporting Burden

Public reporting burden for the following collections of information include the time for reviewing instructions, searching existing data sources, gathering and maintaining the

data needed, and completing and reviewing the collection of information in the provision at FAR 52.223-22 or its equivalent at 52.212–3(t). The contracting officer uses this information to determine whether a prospective contractor is a significant or major contractor and, if so, if the prospective contractor is responsible (see FAR 9.104-3(e)). A prospective contractor that is a significant or major contractor is presumed to be nonresponsible if it represents that it is not in compliance with the GHG inventory, annual climate disclosure, and science-based target setting requirements, as applicable. In such situations the contracting officer will ask for additional information from the prospective contractor to determine what efforts have been made to comply. The Government will also use the disclosures made pursuant to this FAR rule to inform development of policies and programs to reduce climate risks and GHG emissions associated with Federal procurement activities, and to incentivize and enable technologies critical to achieving a national economy and industrial sector that are resilient to the physical and transition risks of climate change and net zero emissions by 2050. As stated in OMB Memorandum M-22-06, to assist the Federal Government in assessing the results of efforts to reduce supply chain emissions, and as requested by CEQ and OMB, GSA will provide periodic recommendations on further actions to reduce supply chain emissions, based on information and data collected through supplier disclosures pursuant to this FAR rule and other publicly available information.

1. First Representation

The representations in the provision at FAR 52.223-22 (and the commercial equivalent at FAR 52.212-3(t)) are being revised to require an offeror, when initially registering or when updating a registration in SAM at https:// www.sam.gov, to represent whether it is a significant or major contractor. A significant contractor is an offeror who received \$7.5 million or more in Federal contract obligations in the prior Federal fiscal year. A major contractor is an offeror who received \$50 million or more in Federal contract obligations in the prior Federal fiscal year. Public reporting burden for this collection of information is estimated to average 0.1 hours per response. The annual reporting burden is estimated as follows:

Respondents: 491,690. Total Annual Responses: 491,690. Total Burden Hours: 49,169.

2. Remaining Representations

If the offeror represents that it is a significant or major contractor, then the offeror is required to complete additional representations in the provision regarding whether it meets an exception and whether it has (itself or through its immediate owner or highestlevel owner) completed a GHG inventory of Scope 1 and 2 emissions, provided an annual climate disclosure, and set a science-based target. If an offeror represents that it publicly discloses an annual climate disclosure or science-based target, it also must report the websites where disclosures and targets are made publicly available. Public reporting burden for this collection of information is estimated to average one hour per response. The annual reporting burden is estimated as follows:

Respondents: 5,766. Total Annual Responses: 5,766. Total Burden Hours: 5,766.

3. GHG Inventory of Scope 1 and 2 Emissions

Unless an exception at 23.XX04(a) applies, a significant or major contractor must (itself or through its immediate owner or highest-level owner) conduct a GHG inventory of the annual Scope 1 and Scope 2 emissions. The significant or major contractor itself must report the results of the most recent GHG inventory in SAM. Public reporting burden for the GHG inventory of Scope 1 and 2 emissions is estimated to average approximately 255 hours per response. The annual reporting burden is estimated as follows:

Respondents: 4,802. Total Annual Responses: 4,802. Total Burden Hours: 1,222,983.

4. Annual Climate Disclosure and Science-Based Targets

Unless an exception at 23.XX04(b) applies, a major contractor must submit an annual climate disclosure and set science-based targets. To make the annual climate disclosure, the major contractor must (itself or through its immediate owner or highest-level owner) conduct a GHG inventory of relevant Scope 3 emissions (in addition to the Scope 1 and 2 inventory), conduct a climate risk assessment, develop disclosures aligned with the Recommendations of the Task Force on Climate Related Financial Risk, and complete relevant portions of the CDP (formerly Carbon Disclosure Project) Climate Change Questionnaire within its previous or current fiscal year. The major contractor must (itself or through its immediate owner or highest-level

owner) also set science-based targets to reduce its emissions and have the science-based targets validated by SBTi within the previous five calendar years. A major contractor will likely support its preparation of the disclosure and setting targets. Public reporting burden for the annual climate disclosure is estimated to average approximately 1,946 hours per response. The annual reporting burden is estimated as follows:

Respondents: 793.

Total Annual Responses: 793. Total Burden Hours: 3,265,025.

B. Request for Comments Regarding Paperwork Burden

Submit comments on this collection of information no later than January 13, 2023 through https:// www.regulations.gov and follow the instructions on the site. All items submitted must cite OMB Control No. 9000-0107, Federal Acquisition Regulation Part 23 Requirements. Comments received generally will be posted without change to https:// www.regulations.gov, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check https://www.regulations.gov, approximately two to three days after submission to verify posting. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202-501-4755 or GSARegSec@gsa.gov.

Public comments are particularly invited on:

- The necessity of this collection of information 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 this collection of information;
- 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 respondents, including the use of automated collection techniques or other forms of information technology.

Requesters may obtain a copy of the supporting statement from the General Services Administration, Regulatory Secretariat Division by calling 202–501–4755 or emailing GSARegSec@gsa.gov. Please cite OMB Control Number 9000–0107, Federal Acquisition Regulation Part 23 Requirements, in all correspondence.

List of Subjects in 48 CFR Parts 1, 4, 9, 23, and 52

Government procurement.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA propose amending 48 CFR parts 1, 4, 9, 23, and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 1, 4, 9, 23, and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 1—FEDERAL ACQUISITION REGULATIONS SYSTEM

■ 2. In section 1.106, amend the table by revising the entry for "52.223–22" to read as follows:

1.106 OMB approval under the Paperwork Reduction Act.

PART 4—ADMINISTRATIVE AND INFORMATION MATTERS

■ 3. Amend section 4.1202 by revising paragraph (a)(26) to read as follows:

4.1202 Solicitation provision and contract clause.

(a) * * *

(26) 52.223–22, Public Disclosure of Climate Information—Representation.

PART 9—CONTRACTOR QUALIFICATIONS

■ 4. Amend section 9.104–1 by revising paragraph (g) to read as follows:

9.104-1 General standards.

* * * * *

- (g) Be otherwise qualified and eligible to receive an award under applicable laws and regulations (for example, see the inverted domestic corporation prohibition at 9.108 and requirements at 9.104–3(e) and subpart 23.XX for certain contractors to disclose climate information).
- 5. Amend section 9.104–3 by adding paragraph (e) to read as follows:

9.104-3 Application of standards.

* * * * *

- (e) Public disclosure of climate information. Starting on the dates specified at 23.XX03(a) and (b), the following procedures apply:
- (1) Except as provided in paragraph (e)(3) of this section, the contracting officer shall presume that a prospective contractor is nonresponsible pursuant to 9.104–1 if the prospective contractor is a significant or major contractor (see definitions in 23.XX02) who has not complied with the policy at 23.XX03 (see procedures at 23.XX05), unless the contracting officer determines that—
- (i) The noncompliance resulted from circumstances properly beyond the prospective contractor's control;
- (ii) The prospective contractor has provided documentation sufficient for purposes of award that demonstrates substantial efforts taken to comply, *e.g.*, the prospective contractor has performed one or more of the actions described in 23.XX03; and
- (iii) The prospective contractor has made a public commitment to comply as soon as possible (within 1 calendar year) on a publicly accessible website as defined at 23.XX02.
- (2) When making the determination, the contracting officer shall—
- (i) Request information from the prospective contractor to determine what efforts it has made to comply and the basis for its failure to comply; and
- (ii) Consider the information provided by the prospective contractor relevant to each requirement at 23.XX03 and determine responsibility based on the prospective contractor's efforts to comply with each requirement.
- (3) Upon making a determination of nonresponsibility with regard to a small business concern, the contracting officer shall refer the matter to the Small Business Administration in accordance with paragraph (d)(1) of this section.
- (4) A significant or major contractor is not subject to the standard in paragraph (e)(1) of this section if—
- (i) It is an entity described in 23.XX04(a):
- (ii) For a major contactor, it is an entity described in 23.XX04(b); or
- (iii) An exemption or waiver described in 23.XX06 applies.

PART 23—ENVIRONMENT, ENERGY AND WATER EFFICIENCY, RENEWABLE ENERGY TECHNOLOGIES, OCCUPATIONAL SAFETY, AND DRUG-FREE WORKPLACE

■ 6. Amend section 23.001 by removing the definition "Greenhouse gases" and adding a definition for "Greenhouse gas" in its place to read as follows:

23.001 Definitions.

Greenhouse gas means carbon dioxide, methane, nitrous oxide, hydrofluorocarbons, perfluorocarbons, nitrogen trifluoride, or sulfur hexafluoride.

■ 7. Revise section 23.800 to read as follows:

23.800 Scope of subpart.

- (a) This subpart sets forth policies and procedures for the acquisition of items
- (1) Contain, use, or are manufactured with ozone-depleting substances; or
- (2) Contain or use high global warming potential hydrofluorocarbons.
- (b) For coverage of public disclosure of climate information, including greenhouse gas emissions, see subpart 23.XX.

23.802 [Amended]

- 8. Amend section 23.802 by—
- a. In paragraph (a), removing the words "release or" and adding "release, or" in its place, and adding the word "and" to the end of the paragraph after the semicolon;
- b. In paragraph (b)(2), removing the semicolon and adding a period in its place; and
- c. Removing paragraphs (c) and (d).
- 9. Revise section 23.804 to read as follows:

23.804 Contract clauses.

Except for contracts for supplies that will be delivered outside the United States and its outlying areas, or contracts for services that will be performed outside the United States and its outlying areas, insert the following clauses:

- (a) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons, in solicitations and contracts for-
- (1) Refrigeration equipment (in product or service code (PSC) 4110);
- (2) Air conditioning equipment (PSC
- (3) Clean agent fire suppression systems/equipment (e.g., installed room flooding systems, portable fire extinguishers, aircraft/tactical vehicle fire/explosion suppression systems) (in
- (4) Bulk refrigerants and fire suppressants (in PSC 6830);
- (5) Solvents, dusters, freezing compounds, mold release agents, and any other miscellaneous chemical specialty that may contain ozonedepleting substances or high global warming potential hydrofluorocarbons (in PSC 6850);

- (6) Corrosion prevention compounds, foam sealants, aerosol mold release agents, and any other preservative or sealing compound that may contain ozone-depleting substances or high global warming potential hydrofluorocarbons (in PSC 8030);
- (7) Fluorocarbon lubricants (primarily aerosols) (in PSC 9150); and
- (8) Any other manufactured end products that may contain or be manufactured with ozone-depleting substances.
- (b) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners, in solicitations and contracts that include the maintenance, service, repair, or disposal of-
- (1) Refrigeration equipment, such as refrigerators, chillers, or freezers; or
- (2) Air conditioners, including air conditioning systems in motor vehicles.
- (c) 52.223-20, Aerosols, in solicitations and contracts-
- (1) For products that may contain high global warming potential hydrofluorocarbons as a propellant, or as a solvent; or
- (2) That involve maintenance or repair of electronic or mechanical devices.
- (d) 52.223–21, Foams, in solicitations and contracts for-
- (1) Products that may contain high global warming potential hydrofluorocarbons or refrigerant blends containing hydrofluorocarbons as a foam blowing agent, such as building foam insulation or appliance foam insulation; or
- (2) Construction of buildings or facilities.
- 10. Add subpart 23.XX to read as follows:

Subpart 23.XX—Public Disclosure of **Climate Information**

Sec.

23.XX00 Scope.

Authorities. 23.XX01

23.XX02 Definitions.

23.XX03 Policy.

23.XX04 Exceptions.

23.XX05 Procedures.

Exemptions and waivers. 23.XX06

23.XX07 Solicitation provision.

Subpart 23.XX—Public Disclosure of **Climate Information**

23.XX00 Scope.

This subpart implements requirements for certain Federal contractors to publicly disclose their greenhouse gas emissions and climaterelated financial risk and to set sciencebased targets to reduce their greenhouse gas emissions.

23.XX01 Authorities.

- (a) Section 1 of Executive Order 13990 of January 20, 2021, Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis.
- (b) Section 206 of Executive Order 14008 of January 27, 2021, Tackling the Climate Crisis at Home and Abroad.
- (c) Section 5(b)(i) of Executive Order 14030 of May 20, 2021, Climate-Related Financial Risk.
- (d) Section 302 of Executive Order 14057 of December 8, 2021, Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability, and section II.1. of the accompanying Office of Management and Budget Memorandum M-22-06.

23.XX02 Definitions.

As used in this subpart— Annual climate disclosure means an entity's set of disclosures that-

- (1) Aligns with— (i) The 2017 Recommendations of the Task Force on Climate-Related Financial Disclosures (TCFD) (see https:// assets.bbhub.io/company/sites/60/2021/ 10/FINAL-2017-TCFD-Report.pdf), which cover governance, strategy, risk management, and metrics and targets (see figure 4 of the 2017 recommendations for an outline of disclosures); and
- (ii) The 2021 TCFD Annex: Implementing the Recommendations of the Task Force on Climate-related Financial Disclosures, which includes updates to reflect the evolution of disclosure practices, approaches, and user needs (see https://assets.bbhub.io/ company/sites/60/2021/07/2021-TCFD-Implementing_Guidance.pdf); and

(2) Includes—

(i) A greenhouse gas inventory of its Scope 1, Scope 2, and relevant Scope 3 emissions: and

(ii) Descriptions of the entity's climate risk assessment process and any risks identified.

Greenhouse gas inventory means a quantified list of an entity's annual greenhouse gas emissions that-

- (1) Represents emissions during a continuous period of 12 months, ending not more than 12 months before the inventory is completed; and
- (2) Is conducted in accordance with the Greenhouse Gas Protocol Corporate Accounting and Reporting Standard, which includes the following, as applicable:
- (i) Greenhouse Gas Protocol Corporate Standard, 2004 revised edition (see https://ghgprotocol.org/sites/default/ files/standards/ghg-protocolrevised.pdf).
- (ii) Required Greenhouse Gases in Inventories: Accounting and Reporting

Amendment, 2013 (see https://www.ghgprotocol.org/sites/default/files/ghgp/NF3-Amendment_052213.pdf).

(iii) GHG Protocol Scope 2 Guidance, 2015 (see https://ghgprotocol.org/sites/ default/files/standards/ Scope%202%20Guidance_Final_

Sept26.pdf).

(iv) GHG Protocol Corporate Value Chain (Scope 3) Accounting and Reporting Standard Guidance, 2011 (see https://ghgprotocol.org/sites/default/ files/standards/Corporate-Value-Chain-Accounting-Reporing-Standard_ 041613_2.pdf).

Highest-level owner means the entity that owns or controls an immediate owner of the offeror, or that owns or controls one or more entities that control an immediate owner of the offeror. No entity owns or exercises control of the highest-level owner.

Immediate owner means an entity, other than the offeror, that has direct control of the offeror. Indicators of control include, but are not limited to, one or more of the following: ownership or interlocking management, identity of interests among family members, shared facilities and equipment, and the common use of employees.

Major contractor means an offeror who received more than \$50 million in total Federal contract obligations (as defined in OMB Circular A–11) in the prior Federal fiscal year as indicated in the System for Award Management at

https://www.sam.gov.

Publicly accessible website means a website that the general public can discover using commonly used search engines and read without cost. It includes a website of the offeror or a website managed by a recognized third-party greenhouse gas emissions

reporting program.

Science-based target means a target for reducing greenhouse gas emissions that is in line with reductions that the latest climate science deems necessary to meet the goals of the Paris Agreement to limit global warming to well below 2°C above pre-industrial levels and pursue efforts to limit warming to 1.5°C (see SBTi frequently asked questions at https://sciencebasedtargets.org/faqs#what-are-science-based-targets). For information on the latest climate science see 2018 Intergovernmental Panel on Climate Change (IPCC) Special Report on 1.5°C at https://www.ipcc.ch/sr15/.

Scope 1 emissions means direct greenhouse gas emissions from sources that are owned or controlled by the reporting entity.

Scope 2 emissions means indirect greenhouse gas emissions associated with the generation of electricity, heating and cooling, or steam, when these are purchased or acquired for the reporting entity's own consumption but occur at sources owned or controlled by another entity.

Scope 3 emissions means greenhouse gas emissions, other than those that are Scope 2 emissions, that are a consequence of the operations of the reporting entity but occur at sources other than those owned or controlled by the entity.

Significant contractor means an offeror who received \$7.5 million or more, but not exceeding \$50 million, in total Federal contract obligations (as defined in OMB Circular A–11) in the prior Federal fiscal year as indicated in the System for Award Management at https://www.sam.gov.

23.XX03 Policy.

The Government's policy is that the contracting officer shall treat a prospective contractor that is a significant or major contractor as nonresponsible under 9.104–3(e), except as provided in sections 23.XX04 and 23.XX06, unless the following requirements are met:

- (a) Significant and major contractors. Starting on [date 1 year after publication of a final rule], the significant or major contractor (see 23.XX02) has—
- (1) Completed (itself or through its immediate owner or highest-level owner) within its current or previous fiscal year a greenhouse gas inventory of its annual Scope 1 and Scope 2 emissions; and
- (2) Reported in the System for Award Management (SAM) (https://www.sam.gov) the total annual Scope 1 and Scope 2 emissions identified through its most recent greenhouse gas inventory.
- (b) Major contractors. Starting on [date 2 years after publication of final rule], the major contractor has (itself or through its immediate owner or highest-level owner)—
- (1) Submitted an annual climate disclosure, as defined in 23.XX02, by completing those portions of the CDP Climate Change Questionnaire that align with the TCFD recommendations as identified by CDP (https://www.cdp.net/en/guidance/how-cdp-is-aligned-to-the-tcfd) within its current or previous fiscal year and made the annual climate disclosure available on a publicly accessible website; and
- (2) Developed a science-based target, as defined in 23.XX02; had the science-based target validated by the Science-Based Targets Initiative (see https://sciencebasedtargets.org/) within the previous 5 calendar years; and made the

validated science-based target available on a publicly accessible website.

23.XX04 Exceptions.

- (a) The requirements in section 23.XX03(a) and (b) do not apply to a significant or major contractor who is—
- (1) An Alaska Native Corporation, a Community Development Corporation, an Indian tribe, a Native Hawaiian Organization, or a Tribally owned concern, as those terms are defined at 13 CFR 124.3;
- (2) A higher education institution (defined as institutions of higher education in the OMB Uniform Guidance at 2 CFR part 200, subpart A, and 20 U.S.C. 1001);
 - (3) A nonprofit research entity;
 - (4) A state or local government; or
- (5) An entity deriving 80 percent or more of its annual revenue from management and operating contracts (see subpart 17.6) that are subject to agency annual site sustainability reporting requirements.
- (b) The requirements in paragraph (b) of section 23.XX03 do not apply to a major contractor who is—
- (1) Considered a small business for the North American Industry Classification System (NAICS) code identified in its SAM registration as its primary NAICS code; or
 - (2) A nonprofit organization.

23.XX05 Procedures.

- (a) Starting on [date 1 year after publication of a final rule], unless an exemption or waiver applies in accordance with section 23.XX06, the contracting officer shall review an offeror's representations in paragraph (d) of the provision at 52.223–22 or its equivalent at 52.212–3(t)(3) (see paragraph (b) of this section) when determining whether the offeror is a responsible prospective contractor (see section 9.104–3).
- (1) Other than a significant or major contractor. If an offeror represents in 52.223–22(d)(1) that it "is not" a significant contractor and "is not" a major contractor, then the offeror is not subject to the policy at 23.XX03 and no other representations are required.
- (2) Significant contractor. If an offeror represents that it "is" a significant contractor (see 52.223–22(d)(1)(i)) and "is not" an excepted entity (see 52.223–22(d)(2)(i)), the following responses indicate that the offeror is in compliance with the policy at 23.XX03(a):

SIGNIFICANT CONTRACTORS

Representations in 52.223-22(d) or equivalent at 52.212-3(t)(3)	Offeror responses
(i) Paragraph (d)(3)(i) or (t)(3)(iii)(A). Greenhouse gas inventory. (ii) Paragraph (d)(3)(ii) or (t)(3)(iii)(B). Greenhouse gas inventory.	Response must be "has". Scope 1 and Scope 2 totals must be provided.
(iii) Paragraph (d)(4) or (t)(3)(iv). Annual climate disclosure.	Response may be "does" or "does not".
(iv) Paragraph (d)(5) or (t)(3)(v). Science-based targets.	Response may be "does" or "does not".

(3) Major contractor. Starting on [date 2 years after publication of a final rule], if an offeror represents that it "is" a

major contractor (see 52.223–22(d)(1)(ii)) and "is not" an excepted entity (see 52.223–22(d)(2)(i)), the

following responses indicate that the offeror is in compliance with the policy at 23.XX03(b):

MAJOR CONTRACTORS

	Offeror responses				
Representations in 52.223–22(d) or equivalent at 52.212–3(t)(3)	Small business or nonprofit organization	Other than small business or non- profit organization			
(i) Paragraph (d)(2)(ii) or (t)(3)(ii)(B). Excepted entities.	If Offeror checked "is" for (A) or (B), then:	If Offeror checked "is not" for (A) and (B), then:			
(ii) Paragraph (d)(3)(i) or (t)(3)(iii)(A). Greenhouse gas inventory	Response must be "has".	Response must be "has".			
(iii) Paragraph (d)(3)(ii) or (t)(3)(iii)(B). Greenhouse gas inventory	Scope 1 and Scope 2 totals must be provided.	Scope 1 and Scope 2 totals must be provided.			
(iv) Paragraph (d)(4) or (t)(3)(iv). Annual climate disclosure	Response may be "does" or "does not".	Response must be "does".			
(v) Para (d)(5) or (t)(3)(v). Science-based targets	Response may be "does" or "does not".	Response must be "does".			

- (b) For an acquisition of commercial products or commercial services, the contracting officer shall look for equivalent representations from a significant or major contractor in the solicitation provision at 52.212–3(t)(3).
- (c) The contracting officer may rely on the offeror's representations in the provisions at 52.223–22(d) or 52.212–3(t)(3) that it is not a significant or major contractor, that it is subject to an exception, or that it is in compliance with the policy at 23.XX03. If the significant or major contractor's representations indicate that the offeror is not in compliance with the policy at 23.XX03, or if the contracting officer questions the representations, then the contracting officer shall follow the procedures at 9.104–3(e) for determining responsibility.

23.XX06 Exemptions and waivers.

- (a) Exemptions. The procedures at 23.XX05 do not apply to acquisitions listed at 4.1102(a) where the offeror or quoter is exempt from the requirement to be registered in System for Award Management at the time an offer or quotation is submitted.
- (b) *Waivers*. The senior procurement executive may provide the following types of waivers:
- (1) Waiver of procedures. The senior procurement executive may waive the procedures at 23.XX05 and the

- requirement to consider whether a significant or major contractor is in compliance with the policy at 23.XX03 when determining responsibility for—
- (i) Facilities, business units, or other defined units for national security purposes; or
- (ii) Emergencies, national security, or other mission essential purposes; and
- (2) Entity waiver. The senior procurement executive may provide a waiver to enable a significant or major contractor to come into compliance with the policy at 23.XX03. The period for such waivers shall not exceed 1 calendar year. Agencies shall make such waivers publicly available on the agency's website.

23.XX07 Solicitation provision.

The contracting officer shall insert the provision at 52.223–22, Public Disclosure of Climate Information—Representation, in solicitations only when 52.204–7, System for Award Management, is included in the solicitation (see 52.204–8, Annual Representations and Certifications).

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 11. Amend section 52.204–08 by revising the date of the provision and paragraph (c)(1)(xix) to read as follows:

52.204–8 Annual Representations and Certifications.

ANNUAL REPRESENTATIONS AND CERTIFICATIONS (DATE)

(c)(1) * * *

(xix) 52.223–22, Public Disclosure of Climate Information—Representation. This provision applies to solicitations that include the clause at 52.204–7.

- 12. Amend section 52.212–3 by—
- a. Revising the date of the provision;
- b. In paragraph (a):
- i. Adding in alphabetical order definitions for "Annual climate disclosure", "Greenhouse gas", and "Greenhouse gas inventory";
- ii. In the definition of "Highest-level owner" removing from the second sentence the words "highest level" and adding "highest-level" in its place;
- iii. Adding in alphabetical order definitions for "Major contractor", "Publicly accessible website", "Science-based target", "Scope 1 emissions", "Scope 2 emissions", "Scope 3 emissions", and "Significant contractor"; and
- c. Revising paragraph (t).The revisions and additions read as follows:

52.212–3 Offeror Representations and Certifications—Commercial Products and Commercial Services.

* * * * *

OFFEROR REPRESENTATIONS AND CERTIFICATIONS-COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES (DATE) * * * * * * *

(a) *Definitions*. As used in this provision—

Annual climate disclosure means an entity's set of disclosures that—

(1) Aligns with—

(i) The 2017 Recommendations of the Task Force on Climate-Related Financial Disclosures (TCFD) (see https://assets.bbhub.io/company/sites/60/2021/10/FINAL-2017-TCFD-Report.pdf), which covers governance, strategy, risk management, and metrics and targets (see figure 4 of the 2017 recommendations for an outline of disclosures); and

(ii) The 2021 TCFD Annex: Implementing the Recommendations of the Task Force on Climate-related Financial Disclosures, which includes updates to reflect the evolution of disclosure practices, approaches, and user needs (see https://assets.bbhub.io/company/sites/60/2021/07/2021-TCFD-Implementing_Guidance.pdf); and

(2) Includes—

(i) A greenhouse gas inventory of its Scope 1, Scope 2, and relevant Scope 3 emissions; and

(ii) Descriptions of the entity's climate risk assessment process and any risks identified.

* * * * *

Greenhouse gas means carbon dioxide, methane, nitrous oxide, hydrofluorocarbons, perfluorocarbons, nitrogen trifluoride, or sulfur hexafluoride.

Greenhouse gas inventory means a quantified list of an entity's annual greenhouse gas emissions that—

(1) Represents emissions during a continuous period of 12 months, ending not more than 12 months before the inventory is completed; and

(2) Is conducted in accordance with the Greenhouse Gas Protocol Corporate Accounting and Reporting Standard, which includes the following, as applicable:

(i) Greenhouse Gas Protocol Corporate Standard, 2004 revised edition (see https://ghgprotocol.org/sites/default/ files/standards/ghg-protocol-

revised.pdf).

(ii) Required Greenhouse Gases in Inventories: Accounting and Reporting Amendment, 2013 (see https://www.ghgprotocol.org/sites/default/files/ghgp/NF3-Amendment_052213.pdf).

(iii) GHG Protocol Scope 2 Guidance, 2015 (see https://ghgprotocol.org/sites/

default/files/standards/ Scope%202%20Guidance_Final_ Sept26.pdf).

(iv) GHG Protocol Corporate Value Chain (Scope 3) Accounting and Reporting Standard Guidance, 2011 (see https://ghgprotocol.org/sites/default/ files/standards/Corporate-Value-Chain-Accounting-Reporing-Standard_ 041613_2.pdf).

* * * * *

Major contractor means an offeror who received more than \$50 million in total Federal contract obligations (as defined in OMB Circular A–11) in the prior Federal fiscal year as indicated in the System for Award Management at https://www.sam.gov.

* * * * *

Publicly accessible website means a website that the general public can discover using commonly used search engines and read without cost. It includes a website of the offeror or a website managed by a recognized third-party greenhouse gas emissions reporting program.

* * * * *

Science-based target means a target for reducing greenhouse gas emissions that is in line with reductions that the latest climate science deems necessary to meet the goals of the Paris Agreement to limit global warming to well below 2°C above pre-industrial levels and pursue efforts to limit warming to 1.5°C (see SBTi frequently asked questions at https://sciencebasedtargets.org/ faqs#what-are-science-based-targets). For information on the latest climate science see 2018 Intergovernmental Panel on Climate Change (IPCC) Special Report on 1.5°C at https://www.ipcc.ch/ sr15/.

Scope 1 emissions means direct greenhouse gas emissions from sources that are owned or controlled by the reporting entity.

Scope 2 emissions means indirect greenhouse gas emissions associated with the generation of electricity, heating and cooling, or steam, when these are purchased or acquired for the reporting entity's own consumption but occur at sources owned or controlled by another entity.

Scope 3 emissions means greenhouse gas emissions, other than those that are Scope 2 emissions, that are a consequence of the operations of the reporting entity but occur at sources other than those owned or controlled by the entity.

* * * * *

Significant contractor means an offeror who received \$7.5 million or more, but not exceeding \$50 million, in total Federal contract obligations (as

defined in OMB Circular A–11) in the prior Federal fiscal year as indicated in the System for Award Management at https://www.sam.gov.

* * * * *

(t) Public Disclosure of Climate Information (Executive Order 14030). Applies in all solicitations that require offerors to register in SAM (12.301(d)(1)).

- (1) Responsibility. Except as provided in paragraph (t)(2) of this provision, an offeror that is a significant or major contractor will be treated as nonresponsible pursuant to FAR section 9.104–3(e) unless the following requirements are met:
- (i) Significant or major contractor. Starting on [date 1 year after publication of a final rule], if the offeror is a significant or major contractor, then the offeror shall have—
- (A) Completed (itself or through its immediate owner or highest-level owner) within its current or previous fiscal year a greenhouse gas inventory of its annual Scope 1 and Scope 2 emissions; and
- (B) Reported in SAM (https://www.sam.gov) the total annual Scope 1 and Scope 2 emissions identified through its most recent greenhouse gas inventory.
- (ii) Major contractor. Starting on [date 2 years after publication of a final rule], if the offeror is a major contractor, then the offeror (itself or through its immediate owner or highest-level owner) shall have completed the following:
- (A) Annual climate disclosure. Submitted its annual climate disclosure, as defined in paragraph (a) of this provision, by completing those portions of the CDP Climate Change Questionnaire that align with the TCFD recommendations as identified by CDP (https://www.cdp.net/en/guidance/how*cdp-is-aligned-to-the-tcfd*) within its current or previous fiscal year and made the annual climate disclosure available on a publicly accessible website. The time periods for submitting the CDP Climate Change Questionnaire are identified at https://www.cdp.net/en/ guidance/guidance-for-companies.
- (B) Science-based target. Developed a science-based target, as defined in paragraph (a) of this provision; had the science-based target validated by the Science-Based Targets Initiative (see https://sciencebasedtargets.org/) within the previous 5 calendar years; and made the validated science-based target available on a publicly accessible website. The validation process and time period are identified at https://sciencebasedtargets.org/set-a-target.

(2) Exceptions. (i) The requirements in paragraphs (t)(1)(i) and (t)(1)(ii) of this provision do not apply to a significant or major contractor who is-

(A) An Alaska Native Corporation, a Community Development Corporation, an Indian tribe, a Native Hawaiian Organization, or a Tribally owned concern, as those terms are defined at 13 CFR 124.3;

- (B) A higher education institution (defined as institutions of higher education in the OMB Uniform Guidance at 2 CFR part 200, subpart A, and 20 U.S.C. 1001);
 - (C) A nonprofit research entity; (D) A state or local government; or
- (E) An entity deriving 80 percent or more of its annual revenue from management and operating contracts (see FAR subpart 17.6) that are subject to agency annual site sustainability reporting requirements.

(ii) The requirements in paragraph (t)(1)(ii) of this provision do not apply to a major contractor who is-

(A) Considered a small business for the North American Industry Classification System (NAICS) code identified in its SAM registration as its primary NAICS code; or

(B) A nonprofit organization.

(3) Representations. The Offeror shall complete the representation at paragraph (t)(3)(i) of this provision. If the Offeror represents in paragraph (t)(3)(i) that it "is" a significant contractor or major contractor, then the Offeror shall complete the representations in paragraphs (t)(3)(ii) through (v).

(i) Significant or major contractor. The Offeror represents the following:

(A) It [] is, [] is not a significant contractor (see definition in paragraph (a) of this provision).

(B) It [] is, [] is not a major contractor (see definition in paragraph (a) of this provision).

(ii) Excepted entities. The Offeror

represents the following:

(A) It [] is, [] is not an excepted entity described in paragraph (t)(2)(i) of this provision.

(B) For the purposes of applying the exception to the requirement of paragraph (t)(1)(ii) of this provision—

- (1) It [] is, [] is not considered a small business for the NAICS code identified in its SAM registration as its primary NAICS code; and
- (2) It [] is, [] is not a nonprofit organization.
- (iii) Greenhouse gas inventory. [Inventory is required for a significant or major contractor, except as provided in paragraph (t)(2)(i) of this provision.] The Offeror represents that—

(A) It [has, [] has not (itself or through its immediate owner or highest-

level owner) completed within its current or previous fiscal year a greenhouse gas inventory of its annual Scope 1 and Scope 2 emissions; and

(B) Its most recent greenhouse gas inventory indicates the following total annual greenhouse gas emissions in metric tons of carbon dioxide equivalent (MT CO2e):

Scope 1 emissions:

[Offeror to enter total MT CO2e]. Scope 2 emissions: _

[Offeror to enter total MT CO2e].

(iv) Annual climate disclosure. [Disclosure is required for a major contractor, except as provided in paragraphs (t)(2)(i) and (t)(2)(ii) of this provision.] The Offeror represents that it its immediate owner or highest-level owner) make available on a publicly accessible website an annual climate disclosure that was completed using the CDP Climate Change Questionnaire in its current or previous fiscal year.

(v) Science-based targets. [Target is required for a major contractor, except as provided in paragraphs (t)(2)(i) and (ii) of this provision.] The Offeror represents that it [] does, [] does not (itself or through its immediate owner or highest-level owner) make available on a publicly accessible website a sciencebased target that has been validated by the Science-Based Targets Initiative within the previous 5 calendar years.

(4) Website(s). If the Offeror checked "does" in paragraph (t)(3)(iv) or (v) of this provision, then the Offeror shall provide the publicly accessible website(s) where the required disclosures and targets are reported: _.

■ 13. Amended section 52.213-4 by ■ a. Revising the date of the clause; and

■ b. In paragraph (b)(1)(xii), removing the phrase "at FAR 23.804(a)(1)" and adding "in FAR 23.804(a)" in its place. The revision reads as follows:

52.213-4 Terms and Conditions-**Simplified Acquisitions (Other Than Commercial Products and Commercial** Services).

Terms and Conditions—Simplified Acquisitions (Other Than Commercial Products and Commercial Services) (DATE)

■ 14. Amend section 52.223–11 by revising the introductory text to read as follows:

52.223-11 Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons.

As prescribed in 23.804(a), insert the following clause:

■ 15. Amend section 52.223-12 by revising the introductory text to read as follows:

52.223-12 Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners.

As prescribed in 23.804(b), insert the following clause:

■ 16. Amend section 52.223-20 by revising the introductory text to read as follows:

52.223-20 Aerosols.

As prescribed in 23.804(c), insert the following clause:

■ 17. Amend section 52.223–21 by revising the introductory text to read as follows:

52.223-21 Foams.

As prescribed in 23.804(d), insert the following clause:

■ 18. Revise section 52.223–22 to read as follows:

52.223-22 Public Disclosure of Climate Information—Representation.

As prescribed in 23.XX07, insert the following provision:

Public Disclosure of Climate Information—Representation (DATE)

(a) Definitions. As used in this provision—

Annual climate disclosure means an entity's set of disclosures that-

(1) Aligns with-

- (i) The 2017 Recommendations of the Task Force on Climate-Related Financial Disclosures (TCFD) (see https:// assets.bbhub.io/company/sites/60/2021/ 10/FINAL-2017-TCFD-Report.pdf), which covers governance, strategy, risk management, and metrics and targets (see figure 4 of the 2017 recommendations for an outline of disclosures): and
- (ii) The 2021 TCFD Annex: Implementing the Recommendations of the Task Force on Climate-related Financial Disclosures, which includes updates to reflect the evolution of disclosure practices, approaches, and user needs (see https://assets.bbhub.io/ company/sites/60/2021/07/2021-TCFD-Implementing_Guidance.pdf); and

(2) Includes-

- (i) A greenhouse gas inventory of its Scope 1, Scope 2, and relevant Scope 3 emissions; and
- (ii) Descriptions of the entity's climate risk assessment process and any risks identified.

Greenhouse gas means carbon dioxide, methane, nitrous oxide, hydrofluorocarbons, perfluorocarbons, nitrogen trifluoride, or sulfur hexafluoride.

Greenhouse gas inventory means a quantified list of an entity's annual greenhouse gas emissions that-

(1) Represents emissions during a continuous period of 12 months, ending not more than 12 months before the inventory is completed; and

(2) Is conducted in accordance with the Greenhouse Gas Protocol Corporate Accounting and Reporting Standard, which includes the following, as

applicable:

(i) Greenhouse Gas Protocol Corporate Standard, 2004 revised edition (see https://ghgprotocol.org/sites/default/ files/standards/ghg-protocolrevised.pdf).

(ii) Required Greenhouse Gases in Inventories: Accounting and Reporting Amendment, 2013 (see https:// www.ghgprotocol.org/sites/default/files/ ghgp/ $N\bar{F}3$ -Amendment_052213.pdf).

(iii) GHG Protocol Scope 2 Guidance, 2015 (see https://ghgprotocol.org/sites/ default/files/standards/ Scope%202%20Guidance_Final_

Sept26.pdf).

(iv) GHG Protocol Corporate Value Chain (Scope 3) Accounting and Reporting Standard Guidance, 2011 (https://ghgprotocol.org/sites/default/ files/standards/Corporate-Value-Chain-Accounting-Reporing-Standard_ 041613 2.pdf).

Highest-level owner means the entity that owns or controls an immediate owner of the offeror, or that owns or controls one or more entities that control an immediate owner of the offeror. No entity owns or exercises control of the highest-level owner.

Immediate owner means an entity, other than the offeror, that has direct control of the offeror. Indicators of control include, but are not limited to, one or more of the following: ownership or interlocking management, identity of interests among family members, shared facilities and equipment, and the common use of employees.

Major contractor means an offeror who received more than \$50 million in total Federal contract obligations (as defined in OMB Circular A-11) in the prior Federal fiscal year as indicated in the System for Award Management at

https://www.sam.gov.

Publicly accessible website means a website that the general public can discover using commonly used search engines and read without cost. It includes a website of the offeror or a website managed by a recognized thirdparty greenhouse gas emissions reporting program.

Science-based target means a target for reducing greenhouse gas emissions

that is in line with reductions that the latest climate science deems necessary to meet the goals of the Paris Agreement to limit global warming to well below 2°C above pre-industrial levels and pursue efforts to limit warming to 1.5°C (see SBTi frequently asked questions at https://sciencebasedtargets.org/ faqs#what-are-science-based-targets). For information on the latest climate science see 2018 Intergovernmental Panel on Climate Change (IPCC) Special Report on 1.5°C at https://www.ipcc.ch/ sr15/.

Scope 1 emissions means direct greenhouse gas emissions from sources that are owned or controlled by the

reporting entity.

Scope 2 emissions means indirect greenhouse gas emissions associated with the generation of electricity, heating and cooling, or steam, when these are purchased or acquired for the reporting entity's own consumption but occur at sources owned or controlled by another entity.

Scope 3 emissions means greenhouse gas emissions, other than those that are Scope 2 emissions, that are a consequence of the operations of the reporting entity but occur at sources other than those owned or controlled by the entity.

Significant contractor means an offeror who received \$7.5 million or more, but not exceeding \$50 million, in total Federal contract obligations (as defined in OMB Circular A-11) in the prior Federal fiscal year as indicated in the System for Award Management at https://www.sam.gov.

(b) Responsibility. Except as provided in paragraph (c) of this provision, an offeror that is a significant or major contractor will be treated as nonresponsible pursuant to Federal Acquisition Regulation (FAR) section 9.104–3(e) unless the following requirements are met:

(1) Significant or major contractor. Starting on [date 1 year after publication] of a final rule], if the offeror is a significant or major contractor, then the

offeror shall have-

(i) Completed (itself or through its immediate owner or highest-level owner) within its current or previous fiscal year a greenhouse gas inventory of its annual Scope 1 and Scope 2 emissions; and

(ii) Reported in the System for Award Management (SAM) the total annual Scope 1 and Scope 2 emissions identified through its most recent greenhouse gas inventory.

(2) Major contractor. Starting on [date 2 years after publication of a final rule], if the offeror is a major contractor, then the offeror (itself or through its

immediate owner or highest-level owner) shall have completed the following:

(i) Annual climate disclosure. Submitted its annual climate disclosure, as defined in paragraph (a) of this provision, by completing those portions of the CDP Climate Change Questionnaire that align with the TCFD recommendations as identified by CDP (https://www.cdp.net/en/guidance/howcdp-is-aligned-to-the-tcfd) within its current or previous fiscal year and made the annual climate disclosure available on a publicly accessible website. The time periods for submitting the CDP Climate Change Questionnaire are identified at https://www.cdp.net/en/ guidance/guidance-for-companies.

(ii) Science-based target. Developed a science-based target, as defined in paragraph (a) of this provision; had the science-based target validated by the Science-Based Targets Initiative (see https://sciencebasedtargets.org/) within the previous 5 calendar years; and made the validated science-based target available on a publicly accessible website. The validation process and time period are identified at https:// sciencebasedtargets.org/set-a-target.

(c) Exceptions. (1) The requirements in paragraphs (b)(1) and (b)(2) of this provision do not apply to a significant

or major contractor who is-

(i) An Alaska Native Corporation, a Community Development Corporation, an Indian tribe, a Native Hawaiian Organization, or a Tribally owned concern, as those terms are defined at 13 CFR 124.3;

- (ii) A higher education institution (defined as institutions of higher education in the OMB Uniform Guidance at 2 CFR part 200, subpart A, and 20 U.S.C. 1001);
 - (iii) A nonprofit research entity;
- (iv) A State or local government; or (v) An entity deriving 80 percent or more of its annual revenue from management and operating contracts (see FAR subpart 17.6) that are subject to agency annual site sustainability reporting requirements.

(2) The requirements in paragraph (b)(2) of this provision do not apply to

a major contractor who is-

(i) Considered a small business for the North American Industry Classification System (NAICS) code identified in its SAM registration as its primary NAICS

(ii) A nonprofit organization.

(d) Representations. [The Offeror shall complete the representation at paragraph (d)(1) of this provision. If the Offeror represents in paragraph (d)(1) that it "is" a significant contractor or major contractor, then the Offeror shall

complete the representations in paragraphs (d)(2) through (d)(5)].

(1) Significant or major contractor. The Offeror represents the following:

- (i) It [] is, [] is not a significant contractor (see definition in paragraph (a) of this provision).
- (ii) It [] is, [] is not a major contractor (see definition in paragraph (a) of this provision).
- (2) Excepted entities. The Offeror represents the following:
- (i) It [] is, [] is not an excepted entity described in paragraph (c)(1) of this provision.
- (ii) For the purposes of applying the exception to the requirements of paragraph (b)(2) of this provision—
- (A) It [] is, [] is not considered a small business for the NAICS code identified in its SAM registration as its primary NAICS code; and
- (B) It [] is, [] is not a nonprofit organization.
- (3) Greenhouse gas inventory. [Inventory is required for a significant or

major contractor, except as provided in paragraph (c)(1) of this provision.] The Offeror represents that—

(i) It [] has, [] has not (itself or through its immediate owner or highestlevel owner) completed within its current or previous fiscal year a greenhouse gas inventory of its annual Scope 1 and Scope 2 emissions; and

(ii) Its most recent greenhouse gas inventory indicates the following total annual greenhouse gas emissions in metric tons of carbon dioxide equivalent (MT CO2e):

Scope 1 emissions: _ [Offeror to enter total MT CO2e]. Scope 2 emissions:

[Offeror to enter total MT CO2e].

(4) Annual climate disclosure.
[Disclosure is required for a major contractor, except as provided in paragraphs (c)(1) and (c)(2) of this provision.] The Offeror represents that it [] does, [] does not (itself or through its immediate owner or highest-level owner) make available on a publicly

accessible website an annual climate disclosure that was completed using the CDP Climate Change Questionnaire within its current or previous fiscal year.

- (5) Science-based target. [Target is required for a major contractor, except as provided in paragraphs (c)(1) and (c)(2) of this provision]. The Offeror represents that it [] does, [] does not (itself or through its immediate owner or highest-level owner) make available on a publicly accessible website a science-based target that has been validated by the Science-Based Targets Initiative within the previous 5 calendar years.
- (e) website(s). If the Offeror checked "does" in paragraphs (d)(4) or (d)(5) of this provision, then the Offeror shall provide the publicly accessible website(s) where the required disclosures and targets are reported: _.

(End of provision)
[FR Doc. 2022–24569 Filed 11–10–22; 8:45 am]

[FR Doc. 2022–24569 Filed 11–10–22; 8:45 am]

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